

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

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

**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: N-Methylpyrrolidone**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 July 17, 2013.**

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

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

Ralph Parod, PH.D., DABT, N-Methylpyrrolidone Producers Group, by letter dated July 12, 2013.

Comment: The proposed PEL of 1 ppm was not a specific recommendation of the Health Expert Advisory Committee (HEAC), but rather was the low end of a range of values submitted to the Feasibility Advisory Committee (FAC) with no scientific justification for any one value. Therefore, the FAC's recommendation that the 1 ppm is feasible lacks credible scientific basis. The Board should direct the HEAC to re-evaluate the available information, especially the human physiologically-based pharmacokinetics (PBPK) model. Although California Office of Environmental Health Hazard Assessment (OEHHA) considers the NMP PBPK model to be premature, the NMP Producers Group, Inc. (Group) believes OEHHA's stated reasons are

unfounded and inadequate to justify exclusion of the NMP PBPK model from the PEL derivation. EPA's Draft Risk Assessment on NMP concludes that on the basis of more recent studies: NMP is of low concern for reproductive toxicity, inhalation exposures were of lower concern than dermal exposures which are of concern only when gloves are not worn, and human exposures should be assessed in terms of the updated PBPK model developed for NMP. Finally, the proposed PEL is not aligned with the 10 ppm American Industrial Hygiene Association (AIHA) workplace environmental exposure limit (WEEL) for NMP.

Response: Then DOSH Chief Len Welsh explained at the June 24, 2009 HEAC meeting that the purpose of Cal/OSHA convened advisory committees is to ensure full discussion of key issues occurs before development of a formal proposal for the Standards Board. Mr. Welsh emphasized that the Division, not HEAC, was responsible for making decisions about specific PELs to propose to the Board. It was therefore absolutely reasonable for the FAC to consider the feasibility of both the 1ppm and 10 ppm proposed NMP PELs, while the Division continued to study the health based evidence that had been discussed in HEAC that supported either level. At the September, 2009 meeting, Mr. Welsh reaffirmed that the Division would carefully consider the recommendations of both the Group and OEHHA regarding the PBPK model. The Board does not agree that the EPA has concluded that the proposed PBPK model for human exposures to NMP is fully developed. Indeed, the EPA Draft Risk Assessment referred to by the Group remains a draft submitted for public comment with a projected completion date at the end of September, 2013. Expressions of uncertainty and reservations about the reproducibility of the proposed PBPK model remain included in the publically available EPA draft, which in any case, is not supposed to be cited or quoted, according to the EPA. Also, this EPA risk assessment is designed as an estimate of NMP exposures during paint stripping only, and does not necessarily apply to exposures that might occur during other occupational tasks. Finally, the WEEL process is different from the HEAC process and not binding upon it. According to the comment from a WEEL committee member at the November, 2007 HEAC minutes, the WEEL NMP recommendation was based upon the WEEL committee's judgment, not upon a formal risk assessment. The 1 ppm recommendation before the Board was derived from a benchmark dose risk assessment.

The Board, therefore, declines to make the recommended change or return the proposal to an advisory process. However, the Board thanks the Group for its contributions to the advisory and rulemaking process, and assures the Group that its position on an appropriate PEL for NMP has been given careful consideration by both the Division and the Board.

Catherine A. Porter, JD, Policy Director, California Healthy Nail Salon Collaborative, by letter dated July 15, 2013.

Comment: Every workday, nail salon workers, predominately women of reproductive age, are exposed to numerous harmful chemicals in nail care products, including NMP. We recommend a PEL of 1 ppm with a Skin notation and required biological monitoring to protect against developmental toxicity and other adverse health effects of NMP. Well-documented and

consistent health hazard information, coupled with scientific evaluation of the relevant data by Cal/EPA OEHHA, has established that inhalation and dermal exposure to NMP can pose a significant risk of developmental damage.

Response: The Board thanks the Healthy Nail Salon Collaborative for its support of the proposed PEL and skin notation for NMP. With regard to the request for biological monitoring, the Board declines to make this change as this request is beyond the scope of this rulemaking.

Dorothy Wigmore, Occupational Health Specialist, Worksafe, by letter dated July 15, 2013.

Comment: Worksafe thanks the Board for adding NMP to its list of hazardous substances, although the process has taken too long since HESIS NMP alert was issued in October of 2006. NMP is considered a reproductive toxin in Europe, and has been classified as such under the REACH rules. One result of this is concentrations greater than 0.1% of NMP in consumer products are banned in Europe. The commenter is critical of the lengthy process and the fact that two PEL numbers were sent to the FAC by Cal/OSHA -- essentially one from the HEAC (1 ppm) and the other from the NMP industry (10 ppm) -- without fulfilling their responsibilities to put forward a health-based recommendation. There is serious concern about the undue influence of industry voices in these important deliberations, and the consequences of delays and extra work for Cal/OSHA and worker and public health advocates.

For greater transparency on the part of the Board and Cal/OSHA, it is recommended that the March 24, 2009 *Draft NMP HEAC Health-Based Assessment and PEL Recommendation* be added to the Final Statement of Reasons. Worksafe repeats its recommendation to lower the PEL for NMP of 0.5 ppm based upon a benchmark concentration derived from three animal studies and the European Union's determinations of NMP's adverse health effects. Finally, there is a typographical error in the Initial Statement of Reasons and Informative Digest which is important to correct for the record. It should be "reproductive" not "productive" toxicity.

Response: Former DOSH Chief Len Welsh addressed the length of the PEL process at the June, 2009 meeting, noting that the HEAC might be the most difficult advisory committee run by the Division. Nonetheless, the time spent, and the thoroughness of the resulting technical review of the state of knowledge on NMP toxicology gives the Board great confidence in the proposed PEL. While two PEL proposals were forwarded to the FAC for consideration, this advancing of the PEL review process to the next stage was possible only because of the thoroughness of the toxicological review that had taken place in HEAC. See the response to Dr. Parod of the NMP Producers Group to the same question.

Regarding the draft HEAC NMP assessment, that document and its earlier version were extensively discussed at HEAC meetings in 2007, 2008 and 2009, and the minutes of these meetings *are* listed in the ISOR as Documents Relied Upon. In other words, the minutes, and not the underlying documents discussed at the meetings, were the documents relied on in crafting this standard. (HEAC did not craft the standard; Division staff relying on the HEAC minutes

did). The Documents Relied Upon in the ISOR also include the studies forming the basis of the analysis in the assessment document, either directly listed or included as references in other Documents Relied Upon. In regard to the recommendation to lower the proposed PEL to 0.5 ppm, the 2009 Worksafe letter that made that recommendation is listed as a Document Relied Upon and the Division fully considered that recommendation before proposing the 1 ppm level based on the more extensive OEHHA, Staples and other key studies discussed during the HEAC process. Finally, the Board acknowledges the typographical errors at the bottom of page 3 of the ISOR and in the Informative Digest (Notice Register, dated May 31, 2013) that the word “productive” indeed should have been “reproductive.”

The Board thanks Worksafe for their participation in this rulemaking process.

Anne Katten, Pesticide and Work Safety Project Director, California Rural Legal Assistance Foundation (CRLA), by letter dated July 16, 2013.

Comment: While glad to see NMP added to the list of hazardous substances with a California-only PEL, note that CRLA joined Worksafe and others in 2009 in calling for a PEL of 0.5 ppm. But to avoid further delay, CRLA now supports the 1 ppm level with a skin notation and required biological monitoring. It has been nearly five years since the HEAC recommendation, and CRLA is concerned by the NMP Producers Group’s proposal to return the matter to HEAC for additional review. The need for a protective standard is urgent because many workers are extensively exposed to NMP due to its widespread use.

Response: The Board thanks the CRLA for its support of the proposed PEL and skin notation for NMP. With regard to the request for biological monitoring, the Board declines to make this change as this request is beyond the scope of this rulemaking.

Rick Kreutzer, MD, Chief of Division of Environmental and Occupational Disease Control, California Department of Public Health (CDPH), by letter dated July 17, 2013.

Comment: The Hazard Evaluation System and Information Service (HESIS), a program of the CDPH, issued a Health Hazard Alert on NMP in 2006 due to the harm NMP causes to the developing fetus in pregnant animals. HESIS participated in the HEAC meetings on NMP, and Dr. Julia Quint, the former Chief of HESIS extensively reviewed the chemical’s toxicity as a HEAC volunteer. Dr. Quint derived a PEL of 1 ppm that accounts for interspecies and intraspecies variability, which we recommend the Board adopt. Use of NMP as a component of paint strippers, graffiti removers, industrial degreasers and as a carrier of pesticides has increased in recent years. Therefore, it is important that NMP be regulated in the workplace.

Response: The Board thanks the CDPH for its support of the proposed NMP PEL. The Board also recognizes and greatly appreciates the efforts and contributions of HESIS and its former Chief Dr. Quint for the work of the HEAC in developing this recommendation.

Julia Quint, PhD, by letter dated July 18, 2013.

Comment: Dr. Quint stated that when she was Chief of HESIS seven years ago, HEIS issued a Health Hazard Advisory on NMP to warn workers of its toxicity. Prior to issuing the advisory, HESIS worked on an EPA funded grant with Dr. Katy Wolf of IRTA to identify safer alternatives to NMP. After retiring from HESIS, Dr. Quint served from 2007 to 2010 on the HEAC and prepared the PEL recommendation document dated October 26, 2009 that provides the scientific basis for the proposed NMP PEL which she requests to be added as a Document Relied Upon. She strongly supports the proposed NMP PEL of 1 ppm with skin notation. This recommendation is consistent with the Board's mandate to assure workers exposed to NMP do not suffer material impairment of health. The 1 ppm PEL is based on quantitative risk analysis (QRA); using this methodology is consistent with the July 1992 11th Circuit Court of Appeals (AFL-CIO vs. OSHA) decision that stated "...OSHA should perform analysis of risk for noncancer endpoints where possible..." The specific basis for support of this proposal is as follows:

1. The proposed NMP PEL is based on strong scientific evidence thoroughly and transparently reviewed, evaluated and discussed by the HEAC from 2007 to 2009. QRA methods consistent with past advisory committees, OSHA, Cal/EPA, OEHHA, and EPA were used. Developmental toxicity, the most sensitive health endpoint for NMP, was used to derive the proposed 1 ppm PEL. Dr. Quint urges the Board to add the HEAC NMP PEL Recommendation document to the "List of documents Relied Upon" in the Final Statement of Reasons, as it describes the process and strong scientific basis used to identify and derive the recommendation.
2. This PEL recommendation will provide important health protections for workers—protections that have existed in California for 12 years for non-occupational NMP exposures. Note, the proposed PEL is the same as derived initially in 2007. The six year delay in promulgating an NMP PEL demonstrates the negative impact of allowing stakeholders to repeatedly develop and use alternative assessment tools to evaluate existing toxicological data, and it also demonstrates the need to leverage the existing resources of OEHHA in the PEL development process. The 2007 HEAC recommendation of a PEL was derived from the same study OEHHA used to develop its NMP Maximum Allowable Dose Level in 2003. A literature review did not identify more recent or more scientifically robust studies.
3. Federal EPA in its TSCA review of NMP used a QRA approach consistent with the approach used in developing the proposed NMP PEL.
4. Unlike the NMP Producers Group, EPA decided not to use the NMP PBPK model due to identified limitations.
5. EPA's TSCA review of NMP found that methodologies that indicated risk of developmental toxicity down to 1 ppm were more reliable than other methodologies consistent with a risk only at somewhat higher level.

Response: The Board thanks Dr. Quint for her comments on the scientific basis for and support of the proposed PEL of 1 ppm for NMP. See the response to Worksafe comment, dated July 15, 2013, regarding the reason for not adding the HEAC NMP PEL Recommendation document as a Document Relied Upon.

Katy Wolf, PhD, Director, Institute for Research and Technical Assistance (IRTA), by letter dated July 17, 2013.

Comment: IRTA has extensive experience in developing and field testing alternatives to NMP in a number of different applications. Alternatives are available in all cases, they perform well and they are cost effective. They include chemical strippers based on benzyl alcohol and a range of non-chemical alternative stripping methods. Alternatives in cleaning applications are even more widely available and, again, cost effective. IRTA has made significant progress on finding alternative graffiti removers and non-chemical alternatives and there is no reason to continue the use of NMP in this application, which has significant exposure potential. Ms. Wolf applauds the Board for proposing to establish a 1 ppm PEL for NMP. This action will provide a signal to workers that NMP is not a “green alternative” and is actually dangerous. The proposed skin notation is even more important and should encourage workers to be more careful.

Response: The Board thanks the IRTA for its support of the proposed PEL and skin notation for NMP.

Dorothy Wigmore, Occupational Health Specialist, Worksafe, by letter dated July 17, 2013.

Comment: The NMP Producers Group’s July 12, 2013 letter brings up several issues Worksafe disputes and wishes to bring to the Board’s attention. First, the claim that the 1 ppm recommendation does not reflect current scientific data on NMP ignores the scientific findings and concerns of the European Union, which, as Worksafe mentioned in its earlier letter, has effectively banned NMP in consumer products and cosmetics in the Union’s 28 countries with tighter workplace use restrictions to follow soon. Worksafe supports Dr. Quint’s toxicological approach, which like the European Union’s actions takes a public health approach. The Board should review the public comment to the European Union’s actions on NMP and will see that the support for restrictions on NMP was very broad while primarily only industries using NMP opposed the actions. Second, the Group misrepresents the roles of the HEAC and Cal/OSHA. HEAC is advisory and does not have to reach consensus or full agreement about a particular recommendation. Cal/OSHA is responsible in the end. Third, a key factor of the far too lengthy NMP advisory process was the NMP Producers Group’s on-going requests to obtain and/or present more information that might affect NMP assessments and modeling approaches, while ignoring the considerable amount of information already existing on these issues. It is inaccurate and disingenuous for the Group to say now that it was ignored, as it was given the delays it

requested for at least two years. The Group's demand that the Board send this PEL proposal back to the HEAC is a classic delaying tactic.

Response: Please see the response to the NMP Producers Group's letter. The Board thanks Worksafe for their participation in this rulemaking process.

Frances Schreiber, National Lawyers Guild Labor & Employment Committee (NLG L&EC), by letter dated July 18, 2013.

Comment: The NLG L&EC strongly supports the NMP PEL recommendation before the Board. The Division's recommendation is supported by the scientific evidence it reviewed, including a report prepared by the HEAC and material submitted by the NMP Producers Group. And the Division conducted its own research. The Division's recommendation of a PEL of 1 ppm should be adopted by the Board. The NMP Producers Group is incorrect in its statement about procedural matters regarding HEAC, which has no statutory mandated expertise. HEAC serves as a group of volunteers assisting a strapped agency in doing research and helping write reports. Both the Division and HESIS are legislatively mandated to recommend standards; the Board should rely on their expertise. Finally, no law requires the Board to accept the HEAC opinion. Advisory committee consensus is not the principle upon which standards are to be set. The California

Labor Code (viz. LC §144.6) mandates that the Division and the Board protect worker health and safety, with all procedures in the development and adoption of standards incorporating that concept. NLG L&EC rejects the manufacturer's contention that their input was ignored and believes further delay is unwarranted.

NLG L&EC urges the Board to promulgate a PEL of 1 ppm for NMP per the recommendation of expert Dr. Julia Quint or per the expert recommendation of the Division.

Response: The Board thanks the NLG L&EC for its comments and support of the proposed PEL for NMP.

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

Julia Quint, PhD.

Comment: Dr. Quint strongly supports the proposed PEL of 1 PPM with a skin notation. She served on the HEAC and prepared the document containing the scientific basis for the PEL, and this document is based on scientific evidence that was transparently reviewed and evaluated by the HEAC. Dr. Quint asked that the document be added to the record. She believes that 1 PPM will provide the protection for a worker that has been there for non-occupational exposures for over 12 years. She indicated that it has taken 6 years for the 1 PPM recommendation to reach the Board because stakeholders have been allowed to develop new data that did not exist when the

process started. Dr. Quint stated that this new data that stakeholders provided had to be re-evaluated by Cal EPA, and this caused further delay. She urged the Board to accept the proposal.

Dr. Quint submitted for the record a copy of the “Draft N-Methylpyrrolidone (NMP) HEAC Health-Based Assessment and PEL Recommendation, October 26, 2009,” that she prepared.

Response: The Board thanks Dr. Quint for her comments on the scientific basis for and support of the proposed PEL and skin notation for NMP. As to including the document Dr. Quint prepared for HEAC, please see the response to Worksafe’s written comments, dated July 15, 2013.

Dan Leacox, Greenberg Traurig.

Comment: Mr. Leacox has a number of clients interested in the PEL process. He witnessed the gauntlet that Dr. Quint went through in the HEAC regarding this proposed PEL. He stated that if a stakeholder felt that they did not get their fair opportunity to get their information included in the record, the stakeholder would be here to explain that to the Board. Mr. Leacox noted that there are times when a stakeholder does not know what they are responding to until a PEL is proposed, so when they respond, new data may be developed or presented in response.

Response: The Board thanks Mr. Leacox for his comments on the PEL advisory process.

Dr. Katy Wolf, Institute for Research and Technical Assistance.

Comment: Dr. Wolf supports the PEL of 1 PPM with a skin notation. She stated that she has worked on finding solvent alternatives and have found cheaper and safer alternatives to NMP. Recently, she has been working on a graffiti removal project where chemicals containing NMP have been put in spray bottles and used to spray it on and remove the graffiti. She indicated that the spray bottles can release the chemical into one’s breathing zone, and when the bottle malfunctions, the chemical can get on one’s hands and arms. Dr. Wolf believes a PEL is needed to communicate that NMP is dangerous.

Response: The Board thanks Dr. Wolfe for her comments and support of the proposed PEL and skin notation for NMP.

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.