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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: N-Methylpyrrolidone (NMP)**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, and ceiling limits. Section 5155 also requires that, for specified substances that 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 establish a PEL for a substance not previously listed in Section 5155, N-Methylpyrrolidone (NMP), Chemical Abstract Service (CAS) Registry Number 872504. In the interest of clarity and ease of reference by the regulated public, the proposed regulatory text lists three additional commonly used names for this substance, along with its CAS Register Number, a unique numeric identifier. The PEL proposed is 1 part per million in air (ppm) as an 8-hour time-weighted average (TWA). The Board believes this PEL is necessary to reduce the risk of developmental effects in the offspring of exposed workers. The Board is also proposing an “S” notation for this substance, indicating that substantial exposure may occur due to contact with skin, mucous membranes, and/or eyes.

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. Consideration of NMP for a PEL originated with concerns of the Hazard Evaluation System and Information Service (HESIS) in the California Department of Public Health (CDPH) with its effects on prenatal development identified in inhalation studies of rats and the fact that it has industrial uses and worker exposures in California. NMP was also identified by the Office of Environmental Health Hazard Assessment (OEHHA) as a substance that should be regulated in the workplace based on its potential for developmental toxicity.

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 under consideration. These advisory committees assist the Division in evaluating and interpreting the studies and other scientific information listed in the Documents Relied Upon section that formed 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 new PEL proposed for NMP was taken up by the Division’s Health Expert Advisory Committee (HEAC) for PELs at meetings starting in November 2007 with discussion concluding at the meeting of September 10, 2009. With assistance from OEHHA, the HEAC discussed scientific information on possible health effects of NMP. After the HEAC discussions on NMP concluded, feasibility and cost issues were taken up at a meeting of the Division’s Feasibility Advisory Committee (FAC) held 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. The website for 2007-2008 meetings is <http://www.dir.ca.gov/dosh/DoshReg/5155Meetings.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 they do not currently include a PEL value for NMP. 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. Since the federal standards were promulgated over 40 years ago, scientific studies with experimental animals have shown that NMP has the potential to harm the developing fetus. 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 NMP 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: (1) 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, and (2) the requirement that all state occupational safety and health rulemaking be channeled through a single entity (the Standards Board).
- Is the least burdensome effective alternative. A PEL higher value than that being proposed in this rulemaking would not be sufficiently effective in reducing the risk of productive toxicity posed to workers by NMP. 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 NMP, 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 NMP Producers Group participated actively in the advisory process, sending a scientific representative to present and discuss information and recommendations with the health committee, and sending a letter that was considered in the advisory committee discussion of cost and feasibility. 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. As a performance based standard, the proposed regulation does not mandate particular methods or practices in order to achieve compliance.

A new Permissible Exposure Limit of 1ppm as an 8-hour TWA is proposed for NMP. An equivalent 8-hour TWA PEL for NMP in units of milligrams per cubic meter (mg/M^3) is also proposed based on the physical conditions listed in footnotes (e) and (f) of Table AC-1 in Section 5155. A "Skin" notation is proposed to be included with the PEL in light of the well-documented and significant extent to which NMP can be absorbed through contact with intact skin. There is currently no PEL for this substance in California regulations.

Major uses of NMP include cleaning of electronics parts in manufacturing operations, stripping of coatings, and removal of graffiti.

In June 2001, NMP was added to the list of chemicals known to the state of California to cause reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as "Proposition 65"). In 2003, OEHHA estimated Maximum Allowable Dose Levels (MADLs) for developmental effects from exposure to NMP by the inhalation and dermal (skin) routes for its listing under Proposition 65 (OEHHA, 2003). The inhalation MADL for NMP was based on the findings of Staples (1990) of a No Observed Adverse Effect Level (NOAEL) of 50 ppm for developmental effects in the offspring of rats exposed 12 weeks prior to mating. In the Staples (1990) study, decreased fetal weight was seen at an exposure level of 116 ppm making this the Lowest Observed Adverse Effect Level (LOAEL) from this study. A 2007 OEHHA document detailed a number of example derivations of a PEL for NMP based on the Staples (1990) report, ranging from 0.4 ppm to 5 ppm depending on the specific exposure time adjustments and uncertainty factors applied in the derivation for extrapolation from the findings in rats to humans.

Over the course of six HEAC meetings from November 2007 to September 2009, significant discussion was held on the results from studies of developmental toxicity in rats and their appropriate interpretation with respect to recommending a health-based PEL value. Details of the discussion of these issues can be found in the minutes for the HEAC meetings in that timeframe noted above. Detailed background information, analysis, and references for the discussion of NMP in the HEAC meetings can be found in the Draft HEAC Health Assessment and PEL Recommendation document for NMP dated October 26, 2009, available at the websites

noted above for the HEAC meeting minutes.

At its September 10, 2009 meeting the HEAC discussion of NMP concluded without agreement among committee members on a single value for a recommendation for a health-based PEL. As a result, the possible values for a PEL considered by the FAC at its meeting December 8, 2009 ranged from 1 ppm (8-hour TWA) as recommended in both the original and the final Draft HEAC Health-Based Assessment Document dated October 26, 2009, to 10 ppm recommended by the NMP Producers Group.

Comment letters for the FAC meeting on NMP were received from the NMP Producers Group and from WorkSafe. The WorkSafe letter cited a report by the Institute for Research and Technical Assistance (IRTA) dated October 2006. The report was prepared as a result of work sponsored by HESIS and the United States Environmental Protection Agency Region IX (EPA) and evaluated NMP uses in consumer product paint stripping, furniture stripping, other chemical stripping activities, and precision cleaning. The IRTA report indicated that it identified safer alternatives for all five of the solvents studied including NMP, most of which are in use by a variety of companies. The IRTA report indicated that the alternatives evaluated in the study are generally, at most, only slightly more costly, and many are less costly than NMP and the other solvents studied. Such alternatives could be one option for achieving compliance with the proposed PEL. The WorkSafe letter pointed specifically to the IRTA finding in precision cleaning that “no-clean” or water-based cleaning options are the best methods for this task and that water-based cleaning can be less costly than using NMP. The WorkSafe letter, and a FAC member in the meeting, also noted the IRTA finding of benzyl alcohol as being an effective alternative for use in stripping operations, with an overall cost level similar to that of NMP.

The comment letter to the FAC from the NMP Producers Group made reference to a number of published studies on worker exposure levels associated with graffiti removal in several European countries, “open system” vapor/aerosol operations such as paint stripping and adhesive bonding again in Europe, and “closed system” vapor operations including washing of lenses and wires (in Japan) as well as a 1991 article on the microelectronics industry in the U.S. indicating exposures mostly in the range of 1 ppm or less (Beaulieu and Schmerber, 1991). The NMP Producers Group letter also indicated that a limited survey of their California customers indicated that NMP is used primarily in closed systems (i.e. with local exhaust ventilation). The Producers Group letter suggested that even though worker exposure values for NMP with both closed and open-vapor systems at these locations appeared to be close to, or below, the 1 ppm level, there was concern that with a PEL in this range these companies might incur substantial costs to purchase and install air monitoring and engineering controls. The letter also suggested that costs could be increased by a PEL at or near 1 ppm necessitating increased frequency of air sampling.

The comment letter of the NMP Producers Group was discussed at the FAC meeting of December 8, 2009. FAC members did not find persuasive the suggestion that a PEL near 1 ppm would be excessively costly in terms of need for additional air sampling, and they noted that no

data had been provided to support the suggestion in the letter of the NMP Producers Group that there could be substantial costs for controls to achieve compliance with a PEL of 1 ppm.

The Board believes a PEL of 1 ppm (8-hour TWA), along with a “Skin” notation, is necessary to prevent effects on the developing fetus based on the NOAEL value of 50 ppm from Staples et al. (1990) and a cumulative uncertainty factor of 60 consistent with OEHHA’s current noncancer risk assessment guidelines (OEHHA, 2008). The Standards Board believes that, as discussed above, the comment letters received and the discussion at the FAC are supportive of the feasibility of the 1 ppm value being proposed for the PEL.

DOCUMENTS RELIED UPON

1. Health Hazard Advisory for N-Methylpyrrolidone (NMP). HESIS. October 2006.
Available at: <http://www.cdph.ca.gov/programs/hesis/Documents/nmp.pdf>
2. 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 2007.
<http://www.cdph.ca.gov/programs/hesis/Documents/riskreport.pdf>
3. Office of Environmental Health Hazard Assessment, Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency. Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for N-Methylpyrrolidone for Dermal and Inhalation Exposures. March 2003.
http://oehha.ca.gov/prop65/law/pdf_zip/NMPMADL31403.pdf
4. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. Technical Support Document for the Derivation of Noncancer Reference Exposure Levels. June 2008.
http://oehha.ca.gov/air/hot_spots/2008/NoncancerTSD_final.pdf
5. Staples R (1990). 1-Methyl-2-pyrrolidone (NMP): Reproductive and developmental toxicity in the rat. E.I. du Pont de Nemours and Company. Haskell Laboratory Report No. 294-90. [Published as Solomon H, Burgess B, Kennedy Jr G, Staples R (1995). 1-Methyl-2-pyrrolidone (NMP): Reproductive and developmental toxicity study by inhalation in the rat. *Drug Chem Toxicol* 18(4), 271-93.]
6. Akrill P, Cocker J, Dixon S (2002). Dermal exposure to aqueous solutions of N-Methyl pyrrolidone. *Toxicol Lett* 134:265-269.
7. WorkSafe, Comments regarding PELs for Substances before Feasibility Advisory Committee Pursuant to Title 8 § 5155 of the California Code of Regulations. November

18, 2009.

8. NMP Producers Group. NMP Exposure Summary. Received by electronic mail dated December 4, 2010.

9. Institute for Research and Technical Assistance. Assessment, Development and Demonstration of Alternatives for Five Emerging Solvents. Prepared for: Hazard Evaluation System & Information Service, California Department of Health Services, under Agreement No. 04-36006 A01, and United States Environmental Protection Agency Pollution Prevention Grant NP-96912401-1. October 2006.
<http://www.irta.us/Five%20Emerging%20Chemicals.pdf>

10. Beaulieu, H.J., Schmerber, K.R. (1991). M-Pyrol™ (NMP) Use in the Microelectronics Industry. *Applied Occupational and Environmental Hygiene*. 6:874-880.

11. Draft Meeting Summary of the HEAC on November 2, 2007, with a list of Members, Assisting Agencies, and Interested Parties.

12. Draft Meeting Summary of the HEAC on January 29, 2008, with a list of Members, Assisting Agencies, and Interested Parties.

13. Draft Meeting Summary of the HEAC on September 5, 2008, with a list of Members, Assisting Agencies, and Interested Parties.

14. Draft Meeting Summary of the HEAC on December 16, 2008, with a list of Members, Assisting Agencies, and Interested Parties.

15. Draft Meeting Summary of the HEAC on March 29, 2009, with a list of Members, Assisting Agencies, and Interested Parties.

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

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

18. 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.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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

The subject proposal is for a new Permissible Exposure Limit (PEL) for N-Methylpyrrolidone (NMP), a chemical that can be a workplace airborne contaminant where it is used. The primary users of NMP are employers in the private industrial and chemical sectors. The exposure limit proposed is consistent with scientific findings and governmental findings of which professional health and safety staff and consultants of these entities should be aware and it is in the range of exposure limitation recommended and discussed in a Health Hazard Advisory for NMP developed in 2006 by the Hazard Evaluation System and Information Service (HESIS) in the California Department of Health Services. Many of the employer entities that would be affected by the PEL proposed for NMP already seek to control employee exposures to the lowest possible level in the interest of business continuity, other more general requirements to protect worker health and safety, and minimization of tort and workers' compensation liability. Therefore, the additional expenditures for these entities to comply with the revised standard are estimated to be insignificant to none.

There was discussion at a public advisory committee meeting on feasibility and cost of the proposed PEL for NMP. Comment letters were received from an organization representing workers, WorkSafe, and from the NMP Producers Group, an association composed of three domestic manufacturers of NMP. The WorkSafe letter focused on a report indicating that effective alternatives to NMP are available at or about the same total cost. Such alternatives could be one option for achieving compliance with the proposed PEL for NMP. The NMP Producers Group provided a number of scientific reports on NMP exposure levels in different

workplace operations and a letter suggesting that while these reports found that exposures in the most common uses of NMP may be in the range of, or below, 1 ppm, there could be costs associated with control measures to achieve and verify compliance with this level as a PEL. However, the Producers Group letter did not provide specific information on these concerns. While some costs may result from the proposed PEL they are not believed to be significant.

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 NMP was discussed, comment letters were submitted by WorkSafe and the NMP Producers Group. Considering these letters the FAC concluded that a PEL of 1 ppm for NMP should be feasible in California and the Standards Board concurs with that assessment.

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 this standard 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 standards.

EFFECT ON SMALL BUSINESSES

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 NMP was discussed by the FAC. This committee concluded that no information had been presented supporting a conclusion that a PEL of 1 ppm would be infeasible in any particular industrial sector or operation. In light of this, the Standards Board believes

there will be no adverse economic impact on small businesses as a result of the PEL proposed for NMP.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The proposed regulation will not have any effect on the creation or elimination of California jobs or the creation or elimination of California businesses or affect the expansion of existing California businesses as a result of the PEL proposed for NMP. The economic impact of the proposed PEL for NMP was discussed by the FAC. This committee concluded that no information had been presented supporting a conclusion that a PEL of 1 ppm would be infeasible in any particular industrial sector or operation. In light of this, the Standards Board believes there will be no adverse economic impact as a result of the PEL proposed for NMP.

Benefits of the Regulation:

Setting a Permissible Exposure Limit for NMP that is up-to-date and consistent with current scientific information and state policies on risk assessment will send appropriate market signals to employers with respect to the costs of illness and injury which chemicals can impose on workers and their families, the government, and society at large. With appropriate market signals, employers may be better able to choose chemicals for use in the workplace that impose less of a burden on workers and society.

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 factors relevant to consideration of a particular value for the PEL proposed in this rulemaking. These discussions are 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).