

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

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**FINAL STATEMENT OF REASONS****CALIFORNIA CODE OF REGULATIONS**

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

Airborne Contaminants

There are no modifications to the information contained in the Initial Statement of Reasons except for the following nonsubstantive modifications which are the result of Board staff evaluation.

Section 5155. Airborne Contaminants

Since its publication in the March 24, 2000, California Registry Notice, Board staff has identified the omission on the form 9 of the instructional phrase, "Amend Section 5155 to read:". Board staff feels that this phrase is an important instruction for publication purposes in Barclay's Official California Code of Regulations.

In addition, a Section 100, Change to the California Code of Regulations, was initiated by Board staff after this rulemaking action was noticed to correct an editorial error in Table AC-1, Section 5155, Airborne Contaminants, of the General Industry Safety Orders (GISO). The Section 100 requested that the text of footnote (q) be deleted from Table AC-1 and that its reference remain as a placeholder. This request was made based on the realization that in 1995, this section was revised to update employee exposure limits to certain chemicals, including methyl bromide. The short-term exposure limit (STEL) for methyl bromide was deleted because the proposed ceiling limit was determined to be more protective. While the STEL for methyl bromide no longer existed in the then current edition of Barclay's, its accompanying footnote, "(q)" was overlooked for deletion and was no longer applicable. Therefore, as a result of this Section 100, approved by the Office of Administrative Law on June 27, 2000, the current version of the regulatory text has changed with regard to footnote (q).

Since this footnote reference has remained as a placeholder, Board staff is proposing a nonsubstantive modification without a 15-day notice pursuant to Government Code, Section 11346.8(c). The modification proposes to insert the text of proposed new footnote "(s)" in place of the reserved footnote (q) and replace any reference to footnote "(s)" with footnote "(q)" in this proposal.

Additional nonsubstantive editorial and formatting modifications are proposed.

The proposed modifications do not change the meaning or requirements of the regulation and are necessary for consistency with the format of Table AC-1, and for clarity purposes.

SUMMARY AND RESPONSE TO ORAL AND WRITTEN COMMENTS

I. Written Comments

Edward J. Kinghorn Jr., President, The Ferroalloys Association by letter dated May 10, 2000.

The attachments to this written comment were found to have ten missing pages following the close of the comment period. The missing pages were subsequently submitted to the Occupational Safety and Health Standards Board (Board) by Mr. Kinghorn and will be considered as part of the original comment for the purposes of this Final Statement of Reasons.

Comment:

Mr Kinghorn requests on behalf of The Ferroalloy Association (TFA), that the Board consider an enclosed proposal prior to making any revision to the existing TLV for manganese and its compounds. (Mr. Kinghorn refers to the existing Threshold Limit Value (TLV), but the Board will assume that Mr. Kinghorn intended to refer to the existing Permissible Exposure Limit (PEL) for manganese as the Board has no existing TLV for manganese.) The letter states that the proposal was previously submitted to the American Conference of Governmental Industrial Hygienists (ACGIH), and that the ACGIH has placed manganese on their list of "Chemical Substances and Other Issues Under Study". TFA requests, given the reconsideration by the ACGIH of the TLV for manganese, that the Board wait for the results of that reconsideration before taking any further action regarding manganese. TFA also requests that the Board independently consider the appropriate PEL for manganese in light of new data and information provided regarding calculation of an appropriate PEL for respirable dust. The letter goes on to summarize the attached proposal as follows:

1. Normal Homeostatic Mechanisms of Manganese Are Well Defined and Normal Levels of Manganese in the Blood Are Well Established.
 - The human system is capable of controlling absorption and retention from daily intake amounts of manganese that range from 2.5 to 9 mg per day.
 - The respirable fraction of manganese in most operations is between 20% and 50% of the airborne manganese. Since the non-respirable fraction does not reach the lung, half or more of the manganese burden from airborne sources will be subjected to the homeostatic controls in the gastrointestinal tract.
 - Only that portion of inhaled manganese that penetrates the deep lung - the respirable dust fraction - is relevant to controlling manganese toxicity.
 - Accordingly, a TLV based on the respirable fraction would provide a more accurate metric for controlling employee exposure to manganese.

2. Central Nervous System Effects in Humans Should be the Signal Effect for Control of Occupational Exposure to Manganese.
 - Overt effects of occupational exposure to manganese are extremely rare in developed countries, and occur only where exposures are at least an order of magnitude above current OSHA limits and two orders of magnitude above the current manganese TLV.
 - Manganism is a condition of the central nervous system characterized by movement disorders, and in more severe cases, by other neurological dysfunction.
 - Manganese does not have significant effects on the lungs at low levels of exposure, as indicated in the epidemiology studies.
 - Objective signs of human reproductive and developmental toxicity are generally not recognized in the literature as a primary effect of excess exposure to manganese at the levels of exposure of current concern, and do not appear in the literature in the absence of observed neurobehavioral effects.

3. Inhalation is the Single Relevant Workplace Exposure Route for Establishing a TLV for Manganese.
 - The potential for occupational exposure to manganese in the United States is created primarily by coming in contact with dust or fumes generated during manganese mining operations and other processing operations, including cutting and welding of steel and bagging and mixture operations for fertilizers and feed.
 - The number of employees in the United States with significant exposure to manganese in other than welding operations is approximately 10,000 or fewer.
 - The physical and chemical properties of manganese make inhalation the most relevant route to assess workplace exposure. Absorption through the skin is not considered to occur to any great extent. Manganese administered by mouth in the inorganic form is slowly and incompletely absorbed in the bloodstream (only a net 2-7% of manganese is absorbed).

4. The TLV for Manganese Should Be Defined in Terms of the Respirable Fraction.
 - Limiting occupational exposure to respirable manganese dust offers the greatest opportunity to control the most sensitive indicators of the exposure. Where the portal of entry results in or increases the potential toxicity of a substance, the TLV should be based on controlling the dose received via that route.
 - The available data shows that the respirable fraction is the better measure of the absorbed dose based on current understanding of the physical and chemical characteristics of manganese and its metabolism.

5. New Data and Better Scientific Understanding of Observed Effects Support a Respirable Limit.
 - Non-clinical central nervous system effects observed at reported, nominal levels of inhaled manganese have failed to manifest themselves as diagnosable illnesses or clinical conditions, or to progress in severity.
 - These effects are not distinguishable in otherwise objectively normal individuals and are reversible.

6. A Safety Factor is not Required for a TLV for Manganese.

- The safe level of exposure to manganese, which is an essential element, is known.
 - Where a safe level is known and occupational exposures will not significantly increase daily manganese body burden outside the known range, an additional safety factor is overly conservative, unnecessary and would yield a scientifically unsupportable exposure limit.
7. The Current Database Supports the Conclusion that Single TLV for All Forms of Inorganic Manganese is Appropriate.
- The difference in toxicity across routes of exposure is predictable from route-specific bioavailability and differences in the valence and chemical form of manganese affect relative bioavailability but not toxicity.
8. The Respirable TLV for Manganese Should be Based on a 30-day Moving Average Instead of a Single Daily, Eight-hour Exposure Limit.
- Overt effects of manganese exposure via inhalation appear not to be significantly related to long term integrated dose, but rather to a time period measured in weeks or months.
 - This suggests that the appropriate period of evaluation for measuring exposure levels is a moving average of several weeks or months in duration.
 - The Association supports a TLV for manganese at 0.2 mg/M^3 and recommends that it be based on a thirty-day moving average, eight-hour time weighted average (TWA).

Finally, TFA asks that the Board carefully consider their request to postpone its actions until ACGIH completes its review.

TFA attached four documents. One is the proposal, and the other three are referred to by the proposal or letter.

Response:

The Ferroalloy Association proposal requests that the Permissible Exposure Limit (PEL) be expressed as a thirty-day moving average of the respirable fraction of daily airborne manganese concentrations. The limit value proposed for this moving average is 0.2 mg/M^3 . This form of an exposure limit is unusual and does not, to our knowledge, have any precedent. While this form of a limit might have value as a recommended limit or guideline, it has a serious deficiency as a limit which must be enforceable. For the Division of Occupational Safety and Health to positively demonstrate that this thirty day average had been exceeded, up to thirty individual respirable concentration measurements would need to be made involving daily site visits by Division compliance officers to the employer's establishment. The Board believes that this form of an exposure limit would be, for all practical purposes, unenforceable.

The Ferroalloy Association states that only the portion of inhaled manganese which penetrates the deep lung, the respirable fraction, is relevant to controlling manganese toxicity. TFA also contends that available data shows that the respirable fraction is the better measure of absorbed dose based on current understanding of the physical and chemical characteristics of manganese and its metabolism. While it does appear that the respirable fraction plays a dominant role in

manganese toxicity, the Board does not agree that the respirable fraction is the only relevant factor in controlling toxicity. TFA states that dusts in most operations have a respirable fraction ranging between 20% and 50% of total airborne particulate. TFA also states that the nonrespirable fraction inhaled will be subjected to the homeostatic controls in the gastrointestinal tract, and that between 2% and 7% of this is absorbed into the blood stream. If an operation had manganese dust at the low end of the range with a respirable fraction of 20%, and 7% of the nonrespirable fraction (80% of the total mass) was absorbed into the blood stream, and all the respirable fraction was absorbed into the blood stream, then 78% of the absorbed dose would occur via the lung and 22% via the nasal/bronchia/GI route. In this case, the absorption via the nasal/bronchia/GI route could not be described as irrelevant. The nonrespirable fraction would contribute to any toxic effect observed. The Board does not agree that the respirable fraction is the only portion of inhaled manganese that is relevant to controlling manganese toxicity.

The Ferroalloy Association states that, since the safe level of exposure to manganese is known, an additional safety factor is unnecessary and recommends an exposure limit of 0.2 mg/M^3 as a respirable fraction of airborne manganese. The Board assumes that TFA considers its recommended level of 0.2 mg/M^3 respirable airborne manganese as that known safe level. TFA states in its proposal that the recommended exposure limit of 0.2 mg/M^3 respirable airborne manganese is supported by the determination of a No-Observed-Adverse-Effect-Level (NOAEL) in a report attached to the proposal. The report attached to the proposal, "Determination of an Occupational Exposure Guideline for Inhaled Manganese", commissioned by TFA and prepared by Drs. Kenny Crump and Harvey Clewell at the KS Crump Group, ICF Kaiser Engineers, Inc., Ruston, Louisiana, describes several methods for determining a NOAEL and recommends the establishment of a 0.2 mg/M^3 respirable dust standard. The method used to determine the NOAEL described in the report is a method to calculate the "benchmark dose". The method is described in detail in appendix 3 of the report. Appendix 3, page A3-5 describes a comparison between the benchmark dose and NOAELs for 424 sets of data which found that, for an additional risk of 0.1, benchmark doses were smaller than the corresponding NOAEL for between 75% and 90% of data sets, and were less than the NOAEL by an average factor of 2.9. The report states the smallest benchmark dose in terms of respirable manganese concentrations from the three epidemiological studies considered was 0.15 mg/M^3 associated with decreased eye-hand coordination, Roels et al.(1992). The recommendation of 0.2 mg/M^3 as a respirable fraction of airborne manganese in the report is based on this and the other benchmark doses calculated.

If exposure at 0.2 mg/M^3 as a respirable fraction of airborne manganese does not produce adverse effects such as decreased eye-hand coordination, then it would be expected that NOAELs based on other studies, which measured exposure in terms of total particulate, would be significantly greater than 0.2 mg/M^3 as total airborne manganese particulate. This is based on TFAs statement that for most operations the respirable fraction is between 20% and 50% of total airborne manganese and that the respirable concentration would therefore be one fifth to one half the concentrations measured in these studies. An abstract for one such study was included in an attachment to the comment. It is on page 13 of the abstracts from the Fifteenth International Neurotoxicology Conference, October 26-29, 1997. The abstract follows:

REVERSIBILITY OF SUBCLINICAL NEUROTOXIC EFFECTS IN A COHORT OF WORKERS EXPOSED TO MANGANESE DIOXIDE. HA Roels, MI Ortega Eslava, A Robert*, E Ceulemans and D Lison. Industrial Toxicology and Occupational Medicine Unit and * Biostatistics Section, Catholic University of Louvain, Brussels, Belgium

In 1987, a cross-sectional study in male workforce (n=92) of a dry alkaline battery plant in Belgium revealed that 20 to 30% of the workers had subclinical neurobehavioral dysfunction associated with inhalation exposure to particulate manganese dioxide (MnO₂). The mean TWA concentration of manganese in inhalable dust (MnT) amounted to 1 mg Mn/m³ and the duration of exposure was 5.3 years on average. An 8-year prospective investigation was conducted in this cohort in order to find out whether extrapyramidal effects, as diagnosed by a standardized eye-hand coordination (EHC) test were reversible when the airborne manganese concentration at the workplace decreased. During the observation period 1987-1995, MnT monitoring (TWA) was implemented on a monthly basis that yielded nearly 1500 personal air samples, while the EHC test was given yearly to assess the precision of the hand-forearm movement (PN1). By the end of the study the initial cohort size had dropped to 34 subjects. The model of unbalanced-measures (PN1) with unstructured covariance matrix and a time varying covariate (log MnT) was the most appropriate to analyze the database; Wald X² statistics were used for testing the effect of time. The decrease of the Mn concentration in the inhalable airborne fraction was significantly associated with an improvement of the PN1 values (total cohort: X²Wald = 8.5, p=0.004; βlog MnT = -6.098 ± 2.096). Similar time trends were found in the three exposure subgroups, but only in the less exposed subgroup the PN1 value was normalized as MnT decreased from 367 µg Mn/m³ (mean of period 1987-1992) to 119 µg Mn/m³ by the end of the study. The prognosis for the two most exposed subgroups (mean MnT of period 1987-1992: 602 and 2047 µg Mn/m³) remains unclear as the recovery of their EHC may be affected by past Mn exposure to such an extent that a persistent partial loss of EHC cannot be ruled out. It should thus be pointed out that the TLV-TWA of 200 µg Mn/m³ for inhalable particulate (ACGIH, 1993) does not provide much of a safety margin, as the LOAEL and NOAEL derived from the present study appeared to be around 400 and 120 µg Mn/m³, respectively.

The authors of this study express the opinion that the ACGIH limit, which is the same value as the total dust limit proposed by the Board, does not provide much of a safety margin. They estimate a NOAEL for total particulate of 0.12 mg/M³. They also estimate the LOAEL at 0.4 mg/M³ as total airborne particulate. This is an unexpected result if an assumption is made that 0.2 mg/M³ as a respirable fraction of airborne manganese is in fact a NOAEL. These results cast doubt on TFA's recommended limit, and offer additional support for the current ACGIH limit.

After reviewing this comment, the Board has decided that it will not postpone action on the PEL for manganese and its compounds until the ACGIH makes its recommendation, for the following

reason. The current ACGIH recommended exposure limit for manganese is 0.2 mg/M^3 total particulate. Following this ACGIH limit would result in exposures to manganese which are less than those which could occur should the ACGIH adopt the limit TFA proposes. The same cannot be said for exposure at the current PEL (5 mg/M^3 total particulate) for manganese in California, as compared to either the current ACGIH limit or the limit proposed by TFA. TFA indicates that for most operations the respirable fraction is 20% to 50% of total airborne manganese particulate. This implies that the total particulate concentration at TFA's proposed limit would likely be in the range of 0.4 to 1.0 mg/M^3 . This is less than concentrations currently permitted in California by nearly an order of magnitude. There is considerable evidence that harmful effects occur at concentrations of 5 mg/M^3 both in the ACGIH documentation for the TLVs and TFA's proposal. To delay action would mean that the harmful effects indicated would continue for those so exposed during the postponement. The Board finds this alternative unacceptable.

Therefore, the Board will not modify or delay the exposure limit for airborne manganese proposed in the notice, for the reasons stated above.

The Board thanks Mr. Kinghorn for his participation in the Board's rulemaking process.

Mel Mirliss, Executive Director, International Diatomite Producers Association by letter dated April 25, 2000.

Comment:

Mr. Mel Mirliss of the International Diatomite Producers Association (IDPA) states in his letter that the Board is proposing that a respirable fraction limit be added to the existing total dust limit for silica, amorphous and diatomaceous earth. The IDPA states that the substances chosen for review were taken from recent editions of the ACGIH TLV booklet, and that the ACGIH recommends a total dust limit value of 10 mg/M^3 and 3 mg/M^3 as respirable dust. The IDPA states that the current recommendations of the ACGIH are more representative of the available science than other recommendations and therefore should be incorporated as stated.

The IDPA states that the document for amorphous silica and diatomaceous earth, *Silica Amorphous-Diatomaceous Earth* (1996), states that "[t]he uncalcined material (diatomaceous earth) seems to have little adverse effect on the lung at the exposure levels that have been observed by the industry during the past and does not produce significant organic disease or toxic effect when the exposures are kept under reasonable control." The IDPA requests that the Board consider this document in its review and adopt the ACGIH's values as listed.

Response:

The Board is proposing the addition of a respirable dust limit to the existing total dust limit. While both types of limits, if adopted, would apply to amorphous silica and diatomaceous earth, they are independent requirements. Different measurement methods are required to assess compliance with each limit and it is possible to exceed one without exceeding the other. The

Informative Digest for this rulemaking explicitly describes the proposed change to the exposure limit for silica, amorphous and diatomaceous earth as the “addition” of a respirable fraction limit. Changes to the existing total dust limit for silica, amorphous and diatomaceous earth were neither described nor proposed. Therefore, the IDPA’s request to increase the existing total dust limit from the current value of 6 mg/M³ to 10 mg/M³ is outside the scope of changes described in the Informative Digest. The IDPA’s comment does, however, support the adoption of the proposed respirable dust limit at 3 mg/M³.

The IDPA supports its request to increase the total dust limit from 6 mg/M³ to 10 mg/M³ with a quote from the ACGIH document for Silica, Amorphous – Diatomaceous Earth. This document was used as a document relied upon in this rulemaking, as described in the Initial Statement of Reasons. The Board has again reviewed this document in considering this comment and believes that the quote used by the IDPA, when seen in its context, does not serve as a basis for increasing the current total dust limit from 6 to 10 mg/M³. The quote is found in the section of the document entitled “TLV Recommendation”. Immediately following the quote there is a description of the history of a diatomaceous earth processing plant in Lompoc, California. This plant is described as having an in-plant diatomite dust standard of 1.05 mg/M³ since 1973 and a dust count limit of 20 mppcf between 1953 and 1973. The document concludes that recent studies have not shown excess rates of lung cancer or non-malignant respiratory disease observed in workers exposed to much higher levels in the 1930s and 1940s. The in-plant level of 1.05 mg/M³ seems to be an example of what the ACGIH document describes as “under reasonable control”. While this study would support the ACGIH total dust limit of 10 mg/M³, it also supports the California total dust limit of 6 mg/M³, because the levels involved in the study are much lower than both these figures. The Board does not find this example cited by the IDPA a useful basis for increasing the current total dust limit from 6 mg/M³ to 10 mg/M³. The IDPA has not provided information that would allow the Board to distinguish 10 mg/M³ as a better and more appropriate total dust limit than the current limit. Therefore, the Board does not believe a modification to the proposed change stated in the notice to increase the total dust limit from 6 mg/M³ to 10 mg/M³ is necessary.

The Board makes time available at each of its meetings for interested parties to propose changes to occupational safety and health standards. The Board suggests that the IDPA consider proposing such a change at a future Board meeting. Also, the Division of Occupational Safety and Health has informed the Board that it will be conducting a general review of airborne contaminant exposure limits soon and will invite the IDPA to participate in that review.

The Board thanks Mr. Mirliss for his participation in the Board’s rulemaking process.

II. Oral Comments

Oral comments received at the May 11, 2000, Public Hearing

Mr. Jere Ingram, Chairman, Occupational Safety and Health Standards Board

Comment:

Chairman Ingram stated that the advisory committee concluded its deliberations in June of 1998. Chairman Ingram asked the Division to check the data on all the proposed changes to see if there is any relevant information that has come to light since the advisory committee concluded its deliberations in order to make sure that what the Board is considering is current.

Response:

The Division has reviewed the substances for which changes are proposed and reported that, while it has found more recent information on the substances with proposed changes, it does not recommend any changes to the proposal at this time or reopening the rulemaking record in order to include the more recent information. The proposed amendments are current with respect to when these chemicals were reviewed by the Advisory Committee. Any changes to the exposure limits for these chemicals since the Advisory Committee last convened will be considered at future Advisory Committee meetings. Therefore, the Board does not recommend any changes to the proposal based on this comment.

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 alternatives 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 proposed action.