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Comments

Advance Notice of Proposed Rulemaking
"Measuring and Controlling Asbestos Exposure"

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INTRODUCTION

The Industrial Minerals Association of North America (IMA-NA) is a recently established trade association serving the interests of six industrial minerals: ball clay, industrial sand, feldspar, mica, soda ash and talc. Thirty-six founding producer member companies are presently members of the IMA-NA – operating more than 200 mining facilities and employing over 5,000 workers.

Although no IMA-NA company is engaged in the production or distribution of asbestos or asbestos containing products, IMA-NA recognizes the critical importance of sound policy and science in regard to the development and application of any standard involving asbestos. Drawing upon the experience of member companies, IMA-NA appreciates this opportunity to submit comments in response to the Mine Safety and Health Administration (MSHA) Advance Notice of Proposed Rulemaking.

The IMA-NA believes the history of asbestos regulation in the United States has been less than ideal. Despite all the attention it receives, the term "asbestos" is not well understood. This uncertainty has lead to inconsistencies in asbestos measurement and **risk** attribution. For decades, non-asbestos mineral particulate has been improperly identified as asbestos, risks have been both overestimated and underestimated, protective measures have been inconsistently applied and well meaning but ill-informed political, legal and media involvement has often been less then helpful.

The IMA-NA agrees with the MSHA that an opportunity exists to benefit from advancements in the understanding of asbestos. The IMA-NA believes, however, that asbestos recognition and risk understanding remain incomplete and the uncertainty should be recognized if this rulemaking initiative were to move forward.

Background

At the request of the U.S. Department of Labor's Office of the Inspector General (OIG), MSHA was asked to revise its existing asbestos standard (developed in the 1970s). The stated purpose of the revision is to utilize the enhanced understanding of asbestos risk and analytical techniques to better protect miners exposed to asbestos in mines. Acting on this OIG request, MSHA has opened a rulemaking process and asked for public comment in the following areas: permissible exposure limit (PEL), analytical method, take-home contamination, and sampling and analysis of asbestos hazards.

MSHA also has asked for comment regarding the significance or appropriateness of a rule change. Interest in this issue was triggered in November 1999, when the *Seattle Post-Intelligencer* published a series of newspaper articles on asbestos-related illnesses and fatalities among people living in Libby, Montana. The articles concerned a surface vermiculite mine owned by W. R. Grace & Company. The miners employed at the Grace mine were exposed to asbestos through the processing of the ore, and carried the dust home on their clothing and in their personal vehicles, thereby allegedly exposing family members.

It should be noted that the health risks to Libby miners had been recognized years before the Seattle newspaper articles, when in the early 1980s MSHA asked the National Institute for Occupational Safety and Health (NIOSH) to investigate potential health problems from vermiculite. Independent studies, published in 1987 by NIOSH and by McDonald in 1986, found excesses of respiratory cancer and mesotheliomas and positive exposure-response relationships for an asbestos mineral belonging to the amphibole group. [1,2] The Libby vermiculite was found to be contaminated with four to six percent tremolite-actinolite fibers.

The mortality experience of Libby miners was a unique situation involving exposure to an exceptionally potent amphibole asbestos capable of inducing lung cancer and mesothelioma. As demonstrated by MSHA's recent sampling survey for asbestos at all existing vermiculite (the Libby mine is now closed), taconite, talc and other mines, the asbestos exposures occurring at Libby are uncharacteristic to other mining operations and the risk experienced by Libby miners do not appear relevant to the rest of the mining industry. Since the spring of 2000, MSHA has taken more than 900 personal asbestos samples at more than 40 mines that were then used to calculate 285 shift-weighted average (SWA) sample results. Excluding the one asbestos mine studied, analysis by phase contrast microscopy (PCM) resulted in only 12 **SWA** total fiber counts that exceeded 0.1 fibers per cubic centimeter of air (f/cc). Using transmission electron microscopy (TEM) to confirm the PCM analyses for actual asbestos no sample exceeded 0.08 f/cc with most (all but **3)** below one-half the OSHA PEL (0.05 f/cc).

The IMA-NA believes this rulemaking is long overdue and does provide an opportunity to consider an appropriate PEL for asbestos in mining that is protective of miners' health and we hope to assist MSHA in this regard. IMA-NA believes, however, that the implied urgency to do so as a result of recent publicity about the Libby vermiculite experience and any attempt to project the risks faced by those miners to the rest of the mining industry is misguided.

Asbestos Permissible Exposure Limit

Recommendation: IMA-NA believes that MSHA should lower its 8 hour time-weighted average permissible exposure limit for asbestos to 0.1 fibers per cubic centimeter (f/cc), and its short exposure limit to 1.0 f/cc over a sampling period of thirty minutes − consistent with the OSHA standard.

Discussion

The 1994-revised OSHA asbestos standard noted that reducing the exposure limit to 0.1 fibers per cubic centimeter would further reduce, but not eliminate, significant risk of asbestos-related disease. The excess lifetime cancer risk at that level was estimated to be 3.4 deaths per 1,000 workers exposed for a working lifetime. With the exception of the one asbestos mine surveyed, MSHA's recent field sampling data show that none of the samples collected exceed OSHA's 8-hour time-weighted average of 0.1 fibers per cc when analyzed by TEM. While preliminary, these results indicate that exposures to asbestos in mining are low and that the cancer risk to miners should be less than OSHA

risk estimates since cumulative working lifetime fiber per cc years in non-asbestos mining will be lower than the cumulative exposures used in the OSHA risk estimate.

We wish to make it very clear that we make this recommendation to adopt the OSHA PEL because of a need to be prudent in the face of uncertainty and in the interest of regulatory consistency, not because of any agreement on our part with the risk estimate adopted by OSHA. A voluminous body of scientific evidence establishes that asbestos exposure increases the risk for asbestosis, lung cancer and mesothelioma. And while asbestos is perhaps the most studied occupational agent, there remains a great deal of uncertainty and controversy regarding its effects and acceptable levels of exposure. Although in our opinion it is not in the interest of any of the parties involved in this rulemaking to debate the adequacy of the OSHA asbestos PEL, MSHA should be aware of and keep in mind that uncertainties and controversies exist. Some of the complexities in defining exposure-response relationships and risks for asbestos-related disease include:

- Uncertainties in exposure estimates in studied workers that are both quantitative and qualitative.
- Extrapolation to low levels of exposure from epidemiological data that involve only high levels of exposure.
- Variability among estimates of risks from various studies.
- Inconsistent or inappropriate adjustment for the possible confounding effects of tobacco smoking.
- Possibility of differences in potency among different types of asbestos.

a Inadequate description and definitions of asbestos exposures in terms of asbestos mineral type and characteristics of fibers that may lead to the inclusion and exclusion of inappropriate fibers, leading to errors in exposure estimates.

Recent articles have suggested that models have overestimated the lung cancer risk from exposure to asbestos[3,4] The matter of the uncertainty and variability of asbestos risk models, as well as the subject of acceptable risk levels of asbestos exposure, was recently reviewed by the Agency for Toxic Substances and Disease Registry (ATSDR). The ATSDR report can be found at Exhibit **A.**

Analytical Method

Recommendation: PCM should continue to be used as a screening tool at the lower PEL (0.1f/cc) but only if fiber characteristics more specific to asbestos are applied. Such a screening approach should ensure actual or probable asbestos fiber exposures observable by light microscopy are recognized and then confirmed by more discriminating analytical methodology – such as electron microscopy. The screening strategy should establish an appropriate action level of the PEL, or employ appropriate morphological characteristics of fiber populations, so as to ensure that asbestiform fibers are distinguished from nonasbestiform fibers. IMA-NA believes this action level can be determined by means of advancements in the understanding of asbestos morphology, and will better control the unnecessary expenditure of time and money for TEM work. TEM should be used for qualitative purposes only – not for quantification purposes – or for comparison to PELs.

Discussion

In its ANPR MSHA requests that parties comment on the availability and cost of analytical services that might be brought about by changes in the analyses of asbestos samples. The current MSHA PEL for asbestos (2.0 f/cc – **8** hr. time-weighted average) involves initial quantification through the use of an all-inclusive "fiber" count by PCM (400 to 450X). In metal and nonmetal mining, fibers are defined as any particulate that exceeds 5 micrometers in length (the traditional 3:1 aspect ratio is omitted from Title 30, *Code of Federal Regulations,* Section 56.5001(b)). If this total count exceeds 1 f/cc (one-half the current MSHA PEL), the sample is then analyzed more rigorously by TEM, SEM or polarizing light microscopy (PLM) to determine whether the "fibers" counted are asbestos.

A determination of asbestos, it is assumed, is based upon the MSHA description or definition of asbestos and the expertise of the analyst. Since very few mining environments reach an all-inclusive 1.0 f/cc level, utilizing MSHA's current fiber counting criteria, subsequent analysis to confirm the identity of the fiber by electron microscopy is rarely necessary. For example, in MSHA's most recent fiber sampling effort (commented on above), not one of the *285* personal SWA samples exceeded 1 f/cc by PCM (including samples from the single asbestos mine sampled).

The DOL OIG report recommended that MSHA "use TEM in its initial analysis to determine if an asbestos sample is over the PEL." If the MSHA PEL were reduced to the OSHA limit, and a "half the PEL" PCM screening approach were employed, more

confirmation by TEM will be required and analytical costs will rise because more mining environments will produce enough particulate longer than 5 micrometers to meet the "half the PEL" screening criterion. Referring again to recent MSHA fiber sampling, it is possible to gain some insight into what this might mean in terms of extra analytical cost.

We understand, and our example assumes, analysis by TEM ranges between $150 and $250 per sample while analysis by PCM for asbestos will range from $12 to $15 per sample. In its recent field sampling activity for asbestos MSHA reports that it has "taken almost 900 samples at more than 40 operations employing more than 4,000 miners." These samples were reduced to 285 SWA sampling results. Assuming that there were exactly 900 samples that required TEM analysis and that the estimated analytical costs above are in the ballpark, analysis of the 900 personal samples in the MSHA data base by TEM exclusively would have cost on the low end $135,000, and on the high end $225,000.

Suppose MSHA were to use a strategy similar to its current use of PCM for screening samples, establish an action level at one half the OSHA PEL., or 0.05 f/cc, and use TEM to confirm the identification of asbestos on samples exceeding the action level. Not having access to the raw data from the "900 samples," we are unable to determine how many of the 900 personal samples exceeded the hypothetical 0.05 f/cc action level. For illustrative purposes, we have removed the MSHA samples from the one asbestos mine surveyed and tallied the number of SWA samples above the 0.05 f/cc criterion to estimate what analytical costs would have been for a PCM screening strategy. Forty-four SWA

samples exceeded the action limit and would be subject to TEM analysis. Using MSHA's current fiber definition for the PCM counting, the cost of PCM analyses for all 900 samples and confirmatory TEM for the 44 samples would have ranged from $17,400 to $24,500. Going one step further, if the screening level were set at the OSHA PEL, or 0.1 f/cc, 12 samples would have been subjected to TEM and the cost range would be $12,600 to $16,500.

Recognizing the limitations of these estimates by not knowing exactly how many personal samples would have been subjected to TEM confirmation, nonetheless, the end result of any of these scenarios using the MSHA data base would be that no overexposures to asbestos at the OSHA standard would have been detected in mines not engaged in asbestos mining and miners would not be subjected to unacceptable risks. So, if TEM had been used to analyze all the samples, the cost for doing so would have been wasted. Using PCM as a screen would have reduced unnecessary cost with no negative impact on risk detection. PCM analysis could be made an even more reliable screening tool by adopting more specific asbestos fiber-counting criteria resulting in further cost containment.

Be assured that in business such a cost difference – ranging from $12,600 on the low end of our example to $225,000 on the high end – for any service (analytical laboratory or other) without receiving added value or benefit is not viewed as a sound business expense. For this and other reasons, the IMA-NA recommends that MSHA employ a screening method using PCM for the screening of asbestos samples with electron microscopy reserved for confirmation of asbestos.

This idea of a PCM screen – especially if it employs more asbestos-specific fiber counting criteria – is so important we wish to comment more about it. We realize there is concern that asbestos fibers below the resolution limit of the light microscope are not counted under PCM, and when present, constitute a false negative PCM finding. Understandably this does cause concern that an undetected health risk exists – and this, in turn, might argue for TEM analysis for every sample – financial impact aside.

In addressing this concern, we found that MSHA's own *285* SWA mine sampling results provide valuable insight regarding the practicality of PCM screening from a risk perspective. In the MSHA database the PCM total fiber counts significantly outnumber the corresponding TEM counts for actual asbestos. However, comparison was available for *50* sample pairs. For mines not engaged in the mining of asbestos, TEM asbestos counts are approximately *5* to *20* times lower than the PCM count. Even in the one asbestos mine with samples analyzed by both PCM and TEM, the TEM asbestos-specific fiber count was approximately one-half that of the PCM count.

We believe this difference demonstrates the significant role non-asbestos elongated particulate - false positive PCM results if you will - play in the mining environment. Because none of the non-asbestos mine TEM data shows an asbestos concentration in excess of or even approaching the OSHA PEL of 0.1 f/cc, concern that actual asbestos not observed by PCM may exist at a level of risk significance is not supported by the Agency's own data. We believe this, in turn, lends support for PCM as an adequately

sensitive approach – one that could be made even more useful with the adoption of more asbestos-specific fiber counting criteria.

In non-mining environments, where processed asbestos containing materials are more often encountered, sub-light asbestos fiber counts (as MSHA has pointed out) have been shown to be much higher then PCM counts for the same exposure – the exact inverse of what we see in the MSHA mine data. In the mining environment, it might be argued that the greatest error from PCM analysis will be from false positives – the counting of elongated particulate that is not asbestos – not from false negatives.

It would be interesting to know how much different the mining PCM counts would have been from the TEM counts, if more discriminating fiber counting criteria had been applied to the PCM counts. It would be our conjecture that the difference between the PCM count and the TEM count would have been very much less. If correct, the need for more costly TEM work would have been reduced and the time and money involved could have been saved or directed to more important safety and health problems. In short, we believe far more could be gained in the mining environment by a more effective PCM screening approach than from exclusive use of TEM, since it does not appear that such an approach would jeopardize the health of miners.

The IMA-NA believes that if MSHA takes full advantage of the improved understanding of what asbestos is (i.e. observable asbestos fiber characteristics with light microscopy), a more asbestos-specific light microscopy screening approach could be established and

PCM could still be used effectively in the mining environment. We are enclosing with these comments reports and articles from the scientific literature that expand on this concept of fiber counting and identification (Exhibits B through J).

It is now well documented that asbestos fibers in air (always appearing as bundles under the light microscopy), samples of bulk materials and fibers from human lung tissue have distinct morphology observable by light microscopy that set them apart from non-asbestos or "nonasbestiform" fibers. Fiber dimension is the most easily distinguishable characteristic and the most common asbestos characteristic that analysts are trained to use in fiber counting. When the dimensions of actual asbestos fibers are better understood, especially on a "population" basis, **IMA-NA** believes light microscopy can more effectively be used as a quick, reliable, inexpensive screening tool.

To take full advantage of this understanding, however, the commonly used, non-risk based, overly broad **3** to 1 aspect ratio, longer than 5-micrometer historical fiber counting scheme must be abandoned. Fiber counts utilizing the 3 to 1 scheme in actual asbestos exposures, such as those involving processed asbestos fibers or asbestos containing material in **OSHA** regulated exposures, include all asbestos fibers (unless a thick fiber bundle is present). Therefore, abandoning this traditional counting criteria in future asbestos monitoring would not significantly impact historical exposure data used in establishing exposure levels or in risk assessment. It would, however, significantly reduce the inclusion of shorter, fatter non-asbestos fibers and reduce the mistaken belief that this aspect ratio "defines" asbestos in the mining environment.

When a population of fibers, for example, longer than 5 or 10 micrometers with widths less than 1 micrometer (a more discriminating index could be 0.5 micrometers) are observed under the light microscope, these fibers are not at all likely to be cleavage fragments – but more likely to be asbestos fibers. When such an observation is made, further identification/confirmation should be required through a more discriminating analytical technique. Current knowledge does support such an "asbestos specific" screening approach. MSHA should carefully consider this if it wishes to minimize unnecessary cost, time and confusion.

Although an effective PCM screening approach could dramatically reduce the need for TEM use, the IMA-NA agrees with MSHA that PCM cannot ultimately confirm the presence of asbestos or provide an adequate indication of asbestos fiber concentration below the resolution limit of the light microscope. TEM should not be used for PEL comparison purposes. We are not aware of any reported TEM asbestos fiber concentrations that have been adequately correlated to disease endpoints of asbestos exposure or to risk. In contrast, PCM asbestos fiber counts have been related to asbestos-related disease, and do form the basis for exposure limit decisions. Moreover, there is no reliable correlation or correction factor that can be applied to convert TEM asbestos fiber counts to PCM fiber counts.

TEM to PCM asbestos fiber counting correlation schemes have been proposed, but the uncertainties and limitations of these schemes are well recognized. Variables such as the

mode of fiber generation (impacting size and number of fiber bundles) and asbestos mineral type (some presenting shorter, thicker fibers than others) must be taken into consideration. In summary, TEM asbestos fiber counts should not be compared to PELs that were developed using PCM fiber counts, since they do not relate occupational exposures to disease outcomes.

The characteristics of what constitutes and distinguishes asbestiform and nonasbestiform minerals were the topic of an OSHA asbestos hearing in 1990, which preceded the 1992 rule. MSHA should review the testimony and docket submissions to this rule and provide guidance to the regulated community and analysts on the characteristics that need to be considered in samples from mining operations in distinguishing asbestiform from nonasbestiform varieties of the serpentine and amphibole mineral groups. A consensus definition from the 1990 rulemaking supported by 16 mineral scientists, many of whom have published extensively in this area - and put forward by the American Mining Congress (now the National Mining Association) and the National Stone Association (now the National Stone, Sand and Gravel Association) - defined asbestos and described characteristics of asbestos fibers. We feel MSHA should adopt this consensus definition as a means of further reducing ambiguity in this area.

We should note that adoption of this consensus definition would not contradict the Agency's or OSHA's current definition, and in fact would build upon it. This additional clarity would only improve analytical specificity. We recommend that MSHA review a report submitted by the American Mining Congress and National Stone Association at the 1990 OSHA hearing entitled *The Asbestiform and Nonasbestiform Mineral Growth Habit*

and Their Relationship to Cancer Studies and the final OSHA rule on *Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite* as published in the *Federal Register* for developing an asbestos-specific definition. These documents are included as Exhibits K and L.

Finally, when asbestos definitions are not clear and not consistent, the ability to properly gauge exposure-response relationships and protect human health is compromised. Despite abundant literature on the subject of "asbestos", the very meaning of the word remains a source of confusion among health professionals, analytical personnel and regulatory agencies. Unless the meaning of the word "asbestos" is made abundantly clear, little else about asbestos can be. The IMA-NA supports the consensus definition found in Exhibit K.

Take-Home Contamination:

Recommendation: **IMA-NA** believes that when an asbestos take-home exposure exists in a mine from any source, **MSHA** should require appropriate control measures. **IMA-NA** plans to comment further in this area after **MSHA** has more fully defined what controls are desirable and how implementation in this area is envisioned.

Asbestos Sampling

Recommendation: **MSHA** should maintain current, established asbestos monitoring protocols in terms of sampling media, sampling flow rates, filter change out and

employ sound industrial hygiene sampling strategies in sampling for asbestos. MSHA should maintain emphasis on full shift monitoring for PEL data comparison as well.

Discussion

The IMA-NA is most concerned with consistency and proper asbestos identification. Changes in sampling variables such as collection flow rates are likely to further confound the usefulness of asbestos fiber counts.

Comparison of asbestos fiber concentrations obtained in ways different than those used to establish the risk linked PEL reduces the reliability of the sample to predict risk. Obtaining higher fiber counts by adjusting collection and analytical practices is not very meaningful if you are not able to make meaningful comparisons between exposure and the risk of disease.

Certainly any changes in asbestos monitoring or analysis that would improve risk recognition are desirable. Such changes, however, should be confirmed before they are implemented. IMA-NA is not aware of any monitoring adjustments at this time that would improve upon the current asbestos monitoring system. Asbestos fiber count variability caused by sampling strategy and analytical approaches should be avoided.

Health Effects of Nonasbestiform Minerals

The IMA-NA wishes to bring to MSHA's attention a decision by her sister agency, OSHA, in 1992 to remove non-asbestiform minerals, namely nonasbestiform tremolite,

anthophyllite, and actinolite, (hereafter referred to as nonasbestiform ATA) from the asbestos standards for general industry and construction. Instead of regulating these minerals as asbestos, OSHA decided that exposure to nonasbestifrorm ATA should be regulated as particulates not otherwise regulated with a PEL of 15 mg/m^3 for total dust and 5 mg/m^3 for respirable dust.

As discussed in the preamble to the standard, OSHA's determination to remove nonasbestiform ATA from the scope of the asbestos standards, was based on the insufficiency of evidence to support determinations that their further inclusion would protect exposed employees from a risk of disease which was the equivalent in incidence and gravity to asbestos related disease, and that removing coverage would pose a significant risk to exposed employees.

OSHA summarized the basis of its findings as follows. Asbestos and nonasbestiform ATA appear to be distinguishable mineral entities on a population basis, and in most instances on a particle basis. The characteristics which differentiate them generally appear to correspond to the properties which may dictate different biologic response. There are mechanistic data from experimental animals exposed to various durable minerals which support counting some particles of non-asbestiform ATA like all asbestos fibers. However, available toxicological and epidemiologic evidence related specifically to nonasbestiform ATA is negative or inconclusive on the issue. Therefore, OSHA found the evidence insufficient to support regulating nonasbestiform ATA as presenting a risk similar in kind and extent to asbestos.

The **IMA-NA** concurs with the decision by **OSHA** in 1992 not to regulate or identify nonasbestiform minerals as asbestos. We recommend that if the issue of the health effects of nonasbestiform minerals were to become an issue that **MSHA** fully review the OSHA rulemaking prior to taking any further action.

Conclusion

IMA-NA believes significant asbestos exposure in US mines not involved in the mining and milling of asbestos is very rare. MSHA's recent assessment of asbestos exposure in mines supports this judgment. Further, despite ongoing ambiguity and controversy regarding the identification and control of "asbestos," enough understanding does exists to properly identify and control hazardous exposure. However, to make the best use of this understanding, lessons of the past must not be overlooked and theories and concepts no longer supported must be abandoned.

Considering the error-ridden history of asbestos regulation in the United States as it relates to a host of non-asbestos minerals, it might be argued that the greatest risk to the mining community is when asbestos is improperly identified and emotionalism is allowed to trump science and reason.

The IMA-NA looks forward to further participation in this rulemaking as **MSHA** further refines and clarifies its intentions.

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Exhibits

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