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COMMENTS

PUBLIC HEARINGS CONCERNING PROPOSED REVISION

OSHA STANDARD §1910.1001 ET SEQ

RELATING TO

OCCUPATIONAL EXPOSURE TO ASBESTOS

(DATE)

PRESENTED ON BEHALF OF

W. R. GRACE & CO.

BY _____
(Officer)

Construction Products Division

4/11/77

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The Construction Products Division of W. R. Grace & Co. (Grace) appreciates this opportunity to testify at these Public Hearings on the Occupational Safety and Health Administration's (OSHA) rulemakings on a revised standard for occupational exposure to asbestos. Our testimony is in response to that proposed standard as published in the October 9, 1975 Federal Register (Volume 40, No. 197, pp. 47652-47665) and as supplemented in the "Reexamination and Update of Information on the Health Effects of Occupational Exposure to Asbestos" ("Reexamination") published by the National Instutute for Occupational Safety and Health (NIOSH) in December, 1976. That supplement was transmitted to the Assistant Secretary of Labor, OSHA on December 1976 by John F. Finklea, M.D., Director of NIOSH.

This statement on behalf of Grace has also been submitted in quadruplicate with the U.S. Department of Labor Docket Officer, with copies to the attention of the Assistant Secretary of Labor, OSHA, and the Director, NIOSH.

I. Current Standard

Grace first wishes to briefly discuss the current standard for occupational exposure to asbestos. The focus is three significant points which carry over into the proposed standard. Grace would request OSHA reconsideration on these points within the context of the existing standard, were a revised standard not now in process. Grace has previously made written review requests of OSHA in this area.

A. Definition It is essential that a standard should exactly define the materials it regulates. However, the definition of asbestos includes minerals which occur in non-fibrous forms. As examples, although Chrysotile occurs only in fibrous habit (non-fibrous being Antigorite or Lizardite), Tremolite occurs both in fibrous and non-fibrous habit. Although there is considerable published human and animal data showing commercial asbestos (such as Chrysotile, Crocidolite and Amosite) are carcinogens, there is no comparable data for Tremolite.

B. Control Programs These are correctly required for potentially hazardous exposures. However, a control program is also specified for all occupational exposures to asbestos, regardless of level of exposure. Although NIOSH acknowledges data demonstrating a dose:response relationship in their Reexamination (p. VI-I) they do not consider the trigger level concept because exposures were not recorded in the occupational exposure phase of the pertinent epidemiological studies. This is a thin basis for mandating that all employers maintain control programs of medical and monitoring expense at trace levels of exposure (such as 0.1 f/ml) never found to pose a carcinogen hazard and far below the permissible (2 f/ml) exposure levels established in the Standard. Practicality requires a trigger level.

C. Labeling Cautionary labeling of hazardous materials is clearly desirable. However, cautionary labeling is required for all materials containing asbestos fibre except where modified by a "bonding agent, coating,

binder, or other material" so that subsequent exposures will not exceed established limits. Although this approach is a practical one for "bound" fibre products, if literally interpreted, it would severely discriminate against bulk materials with trace fibre contamination, even in the case of exposures well below the established limits. It would appear no label is required on a bound product releasing 1.5 f/ml in use but a label would be required on a bulk construction aggregate releasing 0.05 f/ml in use.

Grace recommends that these briefly discussed, specific inconsistencies in the current standard should be noted. As these inconsistencies are repeated in the proposed standard they are discussed in more appropriate detail below.

D. Timing One other general aspect of the current standard should also be noted. That is that a 5 f/ml TLV was in use in the U.S. for the approximately five year period through July, 1976. A 2 f/ml TLV has been effective only for one year since July 1976. Setting aside for a moment the question of whether that TLV should be lowered, it should be noted that U.S. employers have absorbed considerable amounts of capital and operating expense to plan for and implement this recent change from 5 f/ml to 2 f/ml. Setting aside the question of whether it is possible for employers to implement a still lower TLV, another change to a still lower TLV is projected to be geometrically more expensive than the 5 f/ml to 2 f/ml reduction. Niether is any specific resulting health improvement predicted by either OSHA or NIOSH. Thus, a serious question remains: In the absence of emergency conditions or startling new data, can a further reduction be practical at this time given the very recent drop from 5 to 2 f/ml?

II. Proposed Standard

The proposal carries over most elements of the current standard, including the ones discussed above, but with the addition of several new elements and the intensified attention to others. Grace does not feel it is appropriate for us to comment to each and every aspect of the proposal but will instead concentrate our time here today to those points which we believe are of especial interest to us. We do desire to see modifications of the proposed wording on other elements as well, but we believe other employers will cover them in these Hearings and/or did so in their written Commentaries submitted April 9, 1976.

Taking these selected elements in the sequence in which they appear in the proposal, our detailed comments follow. Where the proposed rulemaking is the subject, the paragraph and section are indicated in parentheses following the topic.

A. Toxicological Considerations of Exposure to Asbestos (II, A, B, and C). Of the 42 references cited in the proposed standard, 27 carry a date of 1972 (the date of the current standard) and earlier. In the 42, most do not address the major issue at hand, namely, in what manner are carcinogenic responses related to different exposure levels. Most, instead, repeatedly re-discuss the already well known health effects of years and years

of asbestos exposure at what were probably very high exposures compared with either the current or proposed U.S. standard. Several are "in press," and some still unobtainable. This means that those references not only have never benefited from peer review, but also that those in industry regulated under the proposed standard are prevented access to whatever evidence may be in those references. (This problem also exists with Re-examination references.)

Other references in the proposal dated since 1972 are re-discussions of earlier studies which had already been published in their entirety prior to 1972. Of these, three might merit comment on the basis of "newness."

1. In (25), Newhouse and Berry apply an earlier statistical model to earlier data to project mesothelioma incidence in a British asbestos textile plant closed 1968. No data was available on exposures but they were admittedly "high."

2. In (30), Howard et al followed up on a longitudinal study of British textile workers and reported an increased cancer incidence among relatively recent employees (since 1950). Again, no data was available on exposures. However, as reported to OSHA on April 9, 1976 by Dr. Hans Weill of Tulane University, it should be noted that average work area concentrations were as high as 25 f/ml with standard deviations nearly as large. In no way does this information pertain to hazards at the current or proposed standard levels.

3. In (41) Gilliam, Dement, et al draw the conclusion that fibre exposures below 2 f/ml pose a significant hazard. However, this was a multiple exposure work environment. Other drafts of the same paper reported comingled arsenic, silica and radon daughter exposures at very significant levels which may have eclipsed any disease contribution by the fibres which were present at some unreported level. Differences in control and experimental groups and smoking history have also been noted. This document has such serious shortcomings that the wisdom of placing any credence upon it in this standards setting process is questionable.

In summary, the "recent" data is not relevant to the proposal which follows it. Other data referred to in the "Reexamination" will be mentioned in connection with specific points discussed below.

B. Definitions (b). The proposal definition of asbestos is identical to that in the current standard except for broadening the current mineralogical scope so as to include "...and every product containing any of these minerals." The added words are unsupported and should be deleted for two reasons. First, the language of the proposed standard is in terms of asbestos fibre and asbestos (product). This broadening of the definition of asbestos thus serves no identifiable objective in facilitating understanding of the proposed standard or its enforcement. Second, it seems to greatly expand the scope of what constitutes asbestos. As an example, non-fibrous tremolite occurs widely in the earth's crust. The proposal's revised "and every product containing" definition has the effect of classifying sand

and gravel fill as "asbestos" even when it contains no fibre. This result seems unwarrented, and is probably also unintended. No improvement in employee health would occur as a result. This aspect is discussed again below under labeling (p. 16).

1. The proposed definition perpetuates the current standard's inclusion of all Tremolite as being "asbestos" regardless of whether occurring in fibrous or non-fibrous habit. This is consistent regulatory practice but it is still as much at odds with the mineralogical facts of asbestos as it was in 1972. Tremolite's physical properties are very different from those of commercial asbestos. This fact is illustrated by the following data comparing Tremolite with the predominant North American commercial asbestos, chrysotile. It is abstracted from the current (1975) edition of Industrial Minerals and Rocks, (p. 384) published by the American Institute of Mining, Metallurgical and Petroleum Engineers.

	Chrysotile	Tremolite
Crystal Structure	fibrous and asbestiform	long and thin columnar
Tensile strength, pounds per sq. inch	80,000 to 100,000	1,000 to 8,000
Spinnability	Very Good	Poor
Flexibility	High	Poor
Electric Charge	Positive	Negative

The sharp difference in properties of tremolite versus commercial asbestos such as chrysotile are also apparent in the attached photographs of commercial chrysotile fibre versus tremolite in fibrous form. (Attachment I).

The data and the photographs depict a fundamental difference between Tremolite and commercial asbestos fibres. The fact that most Tremolite is non-fibrous to one side, that Tremolite which is fibrous has startlingly different properties. Short, waxy, blunt, and weak, the tremolite fibres would appear to be a very different level of irritant in the respiratory system than commercial fibres which are long, hard, sharp, and strong. Indeed, the Tremolite fibres, based upon their physical properties would appear to be much less of a tissue irritant than many hard, sharp, abrasive mineral particles of respirable size never regulated as carcinogens.

2. The point of view Grace is speaking from today is that of both a large industrial user of talcs typically containing tremolite, and also from the perspective of Grace's own vermiculite business. Our perspective is thus dual; the employee health concerns and responsibilities of a customer, and as a producer of tremolite-containing products, as well. You are probably familiar with tremolitic talcs, but a brief description of vermiculite would probably be appropriate.

Vermiculite is a soft, low density, naturally-occurring mineral product. Mined and subsequently processed and packaged, vermiculite is

utilized principally for its non-flammable, high insulation properties, in a number of highly critical fire protection and energy conserving insulation applications. Some vermiculite is found with co-occurring strata of tremolite. The tremolite is present in mined vermiculite only in minor amounts. Of the tremolite which may be present, only a (trace) fraction of that is fibrous. Extensive capital and operating expenses have been incurred by Grace in independent efforts to minimize the tremolite contamination, but it is not practical to totally remove it, even if cost were not a consideration. The perspective, then, of Grace's vermiculite business is that although much of the vermiculite we process and sell may have no detectable amounts of tremolite, the possibility continues that some of it may have trace amounts. However, even where present, most of the tremolite (Zero to %) in finished vermiculite is of a non-fibrous nature. Of the tremolite which may be present, only some (Zero to % of tremolite) is of fibrous habit. Of that fibrous portion, only some (Zero to % of tremolite) is in the respirable particle size range of to . Recent experiments in one facility have shown that in one combination of abnormally dusty circumstances purposely created to pose a "torture test," the maximum airborne concentration of fibrous tremolite which could be artifically induced in that case was 1.5 f/ml. However, at that extreme point, the accompanying concentration of total dust was between four and five times permissible levels of the ACGIH.

In summary, a typical tremolite presence in vermiculite is at a low level, if present, and has little or nothing in common with the concentration potential in handling commercial asbestos. Although Grace cannot say there is "none," there may be this "trace amount" present, and vermiculite thus falls within the asbestos standard regardless of the different properties discussed above.

3. As an illustration of the different physical properties of Tremolite and its unsuitability for the purposes where commercial asbestos products are utilized, it should be noted it is not regulated in the United Kingdom. Their "Standards for Asbestos Dust Concentration" as originally promulgated in 1969 and most recently supplemented do not mention tremolite. Their standard instead regulates commercial asbestos fibres at different exposure levels based upon their demonstrated carcinogenicity. Considering that the large proportion of asbestos human studies cited in the proposal are from the U.K., this is a significant point.

4. As noted above, both fibrous and non-fibrous Tremolite are included in the asbestos definition of both the current and proposed standards. The Occupational Safety and Health Act states data shall be utilized to evaluate the health hazards posed by potentially harmful agents. It is noteworthy that no data on tremolite hazard is referenced either in the 1972 Criteria document (76 references) or in the counterpart 1975 Criteria document (42 references). The word tremolite does occur twice in the December 1976 NIOSH "Reexamination" (221 references). Once is in an Appendix table giving optical properties of minerals on page IV-23. The other is a reference to a 1960 study in a Table appearing on page III-32. That reference indicates that "minute" quantities of tremolite have been detected in farm soils in some areas of Bulgaria.

Thus, although John F. Finklea, M.D., Director of NIOSH states in his cover letter to the Reexamination that "...all forms of asbestos, both commercial and non-commercial, are carcinogenic," that statement is unsubstantiated anywhere in that sizeable document or its 221 references, and thus is without basis.

It should be noted Section 6(a)(5) of the Occupational Safety and Health Act does not allow for the regulation of materials for which no documentation has been provided.

5. Although among all these references there is no published study evaluating a carcinogen hazard of tremolite, it should be noted that there are responsible, contraindicating studies. William E. Smith, M.D., "Experimental Studies on Biological Effects of Tremolite Talc on Hamsters" (1973) reported no mesothelioma in animal populations receiving intrapleural injections of talcs containing 50% fibrous tremolite versus a significant mesothelioma incidence in animals receiving injections of the commercial asbestos minerals; Chrysotile, Amosite, Anthophylite and Crocidolite injections.

Gerrit W. H. Schepers, M.D., D. Sci., "The Biological Action of Talc and other Silicate Minerals" (1973), reviewed the mineralogical crystalline formulae and properties of 37 natural Silicates including tremolite and the 4 principal fibrous forms of commercial asbestos (which Smith studied) as well as 10 synthetic types of respirable fibres. He then analyzed the differential biology of all tissue reactions to them. He concluded "...because (Tremolite) has been classified as an amphibole mineral, it has naturally come under suspicion as a theoretical carcinogen. Theory and fact, however, have never matched up in either human experience or animal experimentation." Schepers went on to develop a relative index of pathogenic response among silicates, which placed tremolite at zero with a theoretical maximum index value of ten accorded to exposures of commercial asbestos in conjunction with other minerals.

A population of talc miners and millers in upstate New York has been followed and periodically reported on over the past two decades (AMA Archives of Environmental Health; Schepers 1955; Kleinfeld 1967, and Kleinfeld 1973). These workers had originally received occupational exposures to fibrous tremolite dusts many, many times the current permissible levels. An early report indicated a possible increased incidence of lung cancer. A later update on the same miners showed a distinctly lower incidence of neoplasia at that point although the men had by that time received a progressively longer exposure to tremolite and smoking. This study is clouded on a couple of points insofar as conclusive findings are concerned. The men received phenomenal mixed dust exposures originally and most also had earlier exposures to metal ore, rock, and commercial asbestos dusts. Kleinfeld concluded, however, (1973) that--notwithstanding the study's problems particularly the miners' high exposure (4 to 5 times the then applicable standard of 5 f/ml)--the mortality decline for lung and pleural cancer 1960/69/73 showed that a 5 f/ml standard for tremolite was adequate. Kleinfeld also concluded that tremolite was less hazardous than commercial asbestos at comparable exposures.

Grace understands that another review of this population is under way, though the results are not yet available.

6. There are precedents for treating Tremolite differently than the other minerals grouped with it in the definition.

First, OSHA issued revised fibre evaluation guidelines for the case of fibrous tremolitic talcs in November, 1974 (OSHA Field Memorandum #74-92) together with a letter by (then) Assistant Secretary of Labor, John Stender, to one talc company, R. T. Vanderbilt and Co. The letter gave that company the right to certify their products as asbestos-free (that is containing tremolite, but not fibrous, asbestiform tremolite) if they contained no naturally occurring fibres prior to processing.

Both the field memorandum and the "certification" letter were rescinded January 19, 1977 by (then) Assistant Secretary of Labor Morton Corn. This incident is mentioned not because we are of the belief that one or the other action was consistent or inconsistent with the Asbestos Standard, but because it shows past consideration has been given to tremolite's different position. Actually, the reason for the January 1977 cancellation of the Field Memorandum and Certification letter was an unreleased NIOSH preliminary reevaluation of the upstate New York miners and millers population discussed above. That is the very mine from which the Vanderbilt talc comes. As noted above, the conclusions from this study have changed from time to time and when it is finalized and released by NIOSH we would welcome an opportunity to review it.

It should be noted, however, that the total tremolite analysis (fibrous and non-fibrous) in tremolitic talcs is typically 35% to 50% by weight, a situation that is very different from the minor contamination present in Vermiculite. The point is that even in such large concentrations, tremolite was recognized to be an exception.

Second, the U.S. Bureau of Mines has recognized the inadequacy of asbestos definitions such as that contained in the current and proposed OSHA standards. They removed non-asbestiform tremolite from the Health and Safety Standards, as reflected in the Federal Register of July 1, 1974, pp. 24316/7. In that amendment, the Bureau of Mines acknowledged the opinion that tremolite was "...not as hazardous as chrysotile and other true asbestos minerals." The Mining Enforcement and Safety Administration further stated that non-fibrous and non-asbestiform tremolite were not included within the definition of asbestos (Federal Register, March 10, 1976, p. 10223).

Third, the American Society of Testing of Materials Committee D-34 has developed a Health and Safety Standard (Sections A1.1 to A1.5) for naturally occurring Mineral fibres (asbestos). They recognize the fact tremolite occurs in both asbestiform and non-asbestiform types and specify that only naturally-occurring fibres (not solid tremolite and not non-fibrous cleavage fragments of tremolite) should be counted as asbestos. This is essentially the same judgement reflected in the U.S. Bureau of Mines and Mining Enforcement and Safety interpretations mentioned above.

Fourth, the distinction between true asbestiform fibres and the non-asbestiform minerals included in the asbestos definition was also addressed in a 1976 paper "Asbestos Minerals and Their Nonasbestos Analogs" by Sarkis G. Ampian, Chief, Branch of Cements and Ceramics, Division of Nonmetallic Minerals of the U.S. Bureau of Mines. "It should be noted at the outset that the non-fibrous minerals crystallizing in the radiating or columnar groups of single crystals do not become asbestos through cominution. Characteristically they all lack unique physical properties, such as flexibility and crystallographic properties." (p. 7)

This same distinction was described earlier (1963) by Hans Berger "Asbestos Fundamentals, Their Origin, Properties, Mining, Processing and Utilization" (Chemical Publishing Company, Inc. of New York) differentiating between "tremolite"--the correct mineral designation for the non-fibrous amphibole--and "tremolite asbestos"--an appropriate designation for the infrequently occurring fibrous form. (p. 2)

Our objective in citing these U.S. government and private mineralogical references is to draw attention to the inconsistency of the OSHA asbestos definition. To the extent the standard addresses "fibres" in specific sections of the Standard, the unnecessary inconsistency is to some extent self-correcting. However, the proposed (and current) definition needlessly generates confusion as to what is asbestos, and the inconsistent definition is picked up and used in state regulations and standards, further compounding the error, particularly with respect to tremolite.

Fifth and last on this point, OSHA should note that numerous other concerned individuals besides Grace have independently highlighted the need to treat tremolite differently than the other minerals grouped with it in the definition. These recommendations were contained in comments filed on the proposed standard in April, 1976. A summary, partial sampling includes:

- E. I. DePont de Nemours & Company (pp. 1/3) recommended deletion of non-asbestiform Tremolite from regulation.
- GAF Corporation (p. 2) recommended that the definition of asbestos product should be revised to cover any product containing asbestos fibre where the fibre is not locked in, and in use, application, or handling would release airborne concentrations above permissable levels. This change would not diminish the effective scope of the standard and would avoid attempting to regulate non-fibrous minerals.
- American Mining Congress (pp. 1/3) recommended that non-asbestiform tremolite be deleted from the definition, as well as that the definition include any products containing more than 1% of asbestiform minerals.
- PPG Industries (pp. 3/4) also recommended clarification of the definition of tremolite in relation to Tremolite.
- Union Carbide (p. 5) pointed out the definition's Tremolite inconsistency as well as the likelihood of trace impurities in raw materials.

- Johns-Manville (p. D-2) recommended that non-asbestiform minerals such as Tremolite should be deleted from the definition and went on to point out the wide prevelance of trace impurities.

- Homestake Mining Company (pp. 3/4) recommended clarification of the definition in respect to Tremolite.

- The American Society for Testing and Materials (pp. 2/4) recommended deletion of non-asbestiform minerals such as tremolite.

In summary, Grace suggests to OSHA that the above recommendations by several representative large chemical and mineral products concerns--none of whom have a direct business interest in tremolite or ties with Grace--, together with the government regulatory precedents and independent professional and trade association recommendations, constitute a valid, responsible message which should be heeded on tremolite. We believe OSHA should act in accordance with these precedents and include only that Tremolite in the definition which is in naturally occurring fibres.

7. One change in the proposed Standard seems minor, but Grace believes that it serves no identifiable objective. It may be detrimental in the possible application of the proposed Standard to non-fibrous minerals. The current Standard defines "Asbestos fibres" as those fibres which may be characterized in terms of length and proportion (paragraph (a)), as determined by the method prescribed in paragraph (e). The Proposed Standard, however, defines "Asbestos fibres" as a particulate form of asbestos possessing a minimum length and maximum aspect ratio (paragraph (b)). Grace inquires as to what purpose is served by defining a "fibre" as a "particulate form," especially as the balance of the Proposed Standard is expressed universally with the nomenclature "fibre." As discussed above, there is a considerable amount of description in minerological science as to the characteristics of a "fibre," but there is no similar body of interpretation concerning "particulate form." This change would appear to be towards vagueness instead of preciseness and ordinarily a standard would strive for the latter objective.

In what may have been a related development, a proposal was presented to the Metallic and Non-Metallic Mine Safety Advisory Committee at their 21st Hearings in October, 1976. That proposal would have substituted "mineral particulate" for "asbestos fibre" in the MESA Standard 57.5-H1 for occupational exposure to asbestos. Due both to the lack of any supporting basis and the impractically large enforcement scope (virtually the entire U.S. Mining, Milling, and Processing industry) the proposed change was withdrawn. However, the comments prepared for those Hearings by W. Clark Cooper, M.D., are as pertinent to the proposal's "particulate" terminology as they were to the MESA proposal's "particulate" terminology. He stated "...It is scientifically untenable to proceed from the known effects of commercial asbestos, where for convenience a 3:1 aspect ratio was set as a lower cut-off in defining a fibre, to the conclusion that any particle which is three times longer than it is wide has

properties like asbestos." Dr. Cooper then proceeded to point out the many questions as to validity of the studies of Pott, Guth, and Friedrichs on which NIOSH has placed so much emphasis in their "Reexamination" of the OSHA Asbestos Standard.

This "particulate" for "fibre" terminology change in the proposal would have great possible impact in the case of minerals such as Tremolite, which occur principally in non-fibrous habit. We recommend that the new "particulate" nomenclature be deleted. It serves no identifiable purpose in improving employee health, and it adds needless confusion.

8. At the same time, the evidence should be reviewed on Tremolite in connection with the proposed standard, it would be well to note that "asbestos" is but one of many types of mineral dust concentrations to which employees are exposed. Grace believes employee exposures to high mineral dust concentrations of any kind are a serious subject.

As mentioned immediately above, the Pott, Guth, and Friedrichs studies were given a prominent position in the NIOSH Reexamination in connection with the proposed, new OSHA Asbestos Standard. Those studies involved phenomonally massive interpleural injections (100 mg). In fact, test animal mortality resulting from this dosage was so high, the injections had to be administered in four, successive 25 mg injections over time.

However, the extrapolatability has never been demonstrated of known, massive animal tests to unknown but comparatively very low exposures for man involving a totally different injection mechanism. Such massive tests may or may not be screenings for neoplasia in man. Certainly it would be a favorable indicator if such a massive injection had no harmful effect, but so many widely occurring minerals can give positive results in such animal tests--without even suggestive human data--that their credibility as an indictment is subject to great doubt as a practical matter. The quantities injected may be so massive as to induce mesothelioma with just about any material.

Those studies showed neoplasia induction from massive injections of many widely used mineral products. They included fibrous glass and gypsum. In this connection it should be noted that animal studies involving Tremolite yielded negative results (Smith, mentioned above).

9. Ignoring, for the sake of discussion, the proposal's impact on Grace's approximately 1,600 employees directly associated with the vermiculite business, as well as the approximately 5,000 people working for other employers involved with distribution, sale, use and application of vermiculite products, one may legitimately ask what the positive, offsetting benefits would be to American society by dislocating this number of people--Grace's business interests in the matter to one side. These vermiculite-based products do not serve the role for society that snack foods or toys do when they are judged to be potentially unhealthful or unsafe. Vermiculite-based products are of proven value on a national scope in saving lives through fireproofing, saving scarce energy resources through insulation, and permitting high-yield horticultural/agricultural production

If vermiculite were eliminated from use, in most product applications there are no known substitutes giving comparable performance characteristics. However, the materials most likely to be substituted for vermiculite, although not giving equivalent performance, would principally be: Perlite, Mineral Fibre, and Glass Fibre. In contrast to the evidence on Tremolite reviewed above, it should be noted that those materials all may have potentially greater health hazards than does the vermiculite they would replace. We refer to the silicosis and pneumoconiosis aspects of Perlite, as well as the respiratory impairment and carcinoma potential of all mineral particles, including the man-made fibres. Our point is not that no materials are 100% "safe" to use (much of the evidence on those substitute materials is from animal studies of questionable pertinence, as discussed above). Rather, our point is, considering the evidence reviewed above on Tremolite, Grace is not only hard pressed to identify any employee health benefit from eliminating vermiculite use, but there is basis to fear a potential, comparative employee health hazard as a result. Those substitute materials do not fall under the scope of the Asbestos Standard and thus, unlike Tremolite, are not tarred with the Asbestos brush, but that situation may change over the next five to ten years. In that perspective it would seem unfair--for lack of a better term--to eliminate vermiculite at this time, given the difficulty in establishing data on Tremolite.

C. Exposure Level (c) In this and previous rulemaking proceedings, OSHA has considered the latency of carcinogenic effects, variations in individual susceptibility, and feasibility of "no-effect," or "threshold" exposure levels. The conclusion has been that employee exposures should be reduced to the lowest feasible level. Feasibility has been defined as the lowest level detectable by available analytic techniques, in this instance, optical microscopy. The problem on this aspect of the OSHA proposal is that optical microscopy is not a reliable methodology at airborne concentrations as low as 0.5 f/ml. Optical microscopy, the only practical analytic technique available at this time, is utterly unreliable at concentrations as low as the 0.1 f/ml recommended in the NIOSH Reexamination. It may be one thing for an agency to recommend an exposure standard that is impractical, monitoring wise; they can focus their enforcement monitoring predominantly on workplaces with higher exposure and/or confine their enforcement citations to airborne concentrations sufficiently higher to permit accurate measurement. The problem, however, is fully placed upon employers. They would be confronted with the task of attempting to monitor to those impractically low concentrations, and below, with a sufficient degree of accuracy so as to fulfill their much greater responsibilities as employers.

Grace expects that others will describe the increased frequency and expense of monitoring required at such low exposures. Many fold more workplaces will be required to receive scheduled monitoring. The amount of monitoring per workplace would also be increased many times in an attempt to compensate for the poor accuracy of the individual samples. Rather than dwell upon this vastly increased monitoring, its expense, and the dubious value of the activity, Grace will instead make a few comments on the problems. As the regulated employers we cannot beg the issue as can the enforcement agency, but would instead have to expend the effort regardless of mill returns.

1. Background concentration values are sufficiently high in many instances that a considerable "headstart" already exists in the ambient before one

attempts to measure incremental contribution at the workplace. Most studies of ambient levels have been done in terms of electron microscopy technique in lieu of optical microscopy. The conversion factor from nanograms mass/m^3 to fibres counted/ml is approximate at best, and the conversion factor varies greatly by type of fibre, length, and aspect ratio.

However, taking the Reexamination's six conversion factors (pp. IV-14/15) and averaging indicates a possible index of 1 ng $\tilde{=}$ 5,100 fibres. Arbitrarily halving this to compensate for the effects of the Nicholson (1973) Study (which cited an average ng to fibre conversion ratio of 30,600) and dividing by 1,000,000 ml/M^3 yields an approximate conversion factor of .0025 for converting ng/M^3 to f/ml. This may be high or low, but it is a conservative average of the data prescribed by NIOSH. NIOSH cites Selikoff as a source in this matter, he having estimated a nanogram equivalency of one million fibres; so, if a factor of 2500 f/nanogram is off-target it would seem to be on the conservative side.

In their Reexamination, they present the detailed results of two major ambient studies in U.S. areas, Selikoff et al (1972) in Table 7 (p. IV-29), and Fairless (1974) in Table 10 (p. IV-32). Applying the rule of thumb conversion factor of 1 ng/M^3 $\tilde{=}$ .0025 f/ml to the mean values in those studies indicates average backgrounds of 0.02 f/ml to 0.08 f/ml for Selikoff and Fairless. It should be noted those are averages. Many backgrounds were much higher, up to an indicated 0.25 f/ml.

We apologize for this digression in conversion factor derivation, but we feel the question of how high U.S. ambients may be in terms of the same measurement system as employed by the Standard is important. The point here is that ambients are high enough to be a significant factor. Actually, Grace has recorded background concentrations as high as those indicated above. We wish this were not so. The uncontrolled pervasiveness of asbestos fibres in our environment is not a basis for considering potentially controllable additions lightly. However, this phenomenon is a fact of life. OSHA could perhaps subtract backgrounds from the values found in workplace monitoring, but the point is that ambients can be a fair percent of workplace values, and at these low concentrations the error associated with the measurement of either is great.

2. Field monitoring procedures and the subsequent laboratory analysis by optical microscopy are imprecise. That imprecision increases as the airborne concentration becomes lower. There are a number of studies illustrating this variability, both from government and private professionals.

G. S. Rajhaus and G. M. Brogg (AIHA Journal, December 1975) analyzed the variability measurements under field conditions. Their standard deviation varied from 0.4 to 1.2 f/ml.

Company test data developed by Grace shows that the measurement of airborne concentrations is subject to considerable variation, even under relatively idealized, closed-room test conditions. Sample collection must take place in close proximity to the point source of fibre release in order to minimize variability in sample collection. Multiple samples taken simultaneously the same close range from the point source may display a standard deviation + x f/ml of the average value at airborne concentrations averaging y f/ml.

This variability increases at lower concentrations and is only partially compensated for by counting to a higher number of fields and/or by taking samples whose duration is many, many times the 15 minute duration mentioned in paragraph (b) of the proposed standard.

When samples are taken ten to fifteen feet from the point source under controlled, non-field conditions, variations of 3 to 8 fold are recorded at immediately adjacent locations. When one is monitoring under field conditions with uncontrolled air circulation and intermittent or varying point sources of fibre emission, the measurement process is subject to such great variation at fibre levels below 2 f/ml that the concept of 0.5 f/ml is quite unfeasible. Although NIOSH, in their Reexamination, bases their exposure recommendations upon the capabilities of the very same measurement process we are talking about, it should be noted that their basis (such as p. IV-25, "Reexamination") is based upon idealized, "theoretical minimums" of detectable fibre concentrations. Grace, speaking as a employer with continuing responsibilities and experience in not only detecting but quantifying fibre concentrations under field concentrations, must take specific exception with the proposal's statement that 0.5 f/ml is a viable exposure threshold, measurement-wise.

3. The samples gathered in the field are then subjected to several types of error when analyzed in the laboratory, the principal one there being counter bias and error. Setting aside, for a moment, measurement variations induced by the sample gathering phase of the method, let us consider the laboratory evaluation phase specifically. Ortiz et al (Journal of the American Industrial Hygiene Association, 1975) reviewed this area of variability in some detail in a paper supported by NIOSH. Referring to data generated by NIOSH in their Proficiency Analytic Testing Program (a NIOSH program to demonstrate laboratory competency in evaluating airborne asbestos fibre concentrations), Ortiz et al advised "...that under the ideal conditions of several experienced counters counting the same wedges, using the same optics, variations as large as 50% are observed."

Ortiz et al also reported the results of the NIOSH PAT program comparing laboratories counting the same identical samples. After eliminating 5 to 10% of the results on the basis that they were abnormally high or low counts, the remainder still had coefficients of variation typically ± 50% to 60%. Considering this variability on evaluating filters produced under controlled conditions, the practicality of a 0.5 f/ml standard is ruled out. To these fibre counting variations of ± 50 to 60%, one must also add higher variations which occur in field sample collection, as well as variations induced by other parts of the measurement process not discussed in detail here (sample preparation, microscope type and calibration, counting rules, and natural variation). Although it is feasible to discriminate an exposure of 2 f/ml from 5 f/ml or 1 f/ml by existing technology, it is not practical to quantify and discriminate between an exposure of 0.5 f/ml from 1 f/ml or 0.25 f/ml under field conditions with reliability. Reliable discrimination among concentrations around 0.1 f/ml, under field conditions, is patently impossible.

4. This only available monitoring method, optical microscopy, is particularly difficult to use at low concentrations. Plate-like mineral particles

on edge can and do become confused with asbestiform fibres. This error is especially encountered when the laboratory technician is evaluating low concentrations and there is little material on the microscope reticle area to be counted. Comparisons between adjacent particles is not possible, and the probability of counting a non-fibre as a fibre is aggravated at low concentrations.

This difficulty has previously been noted with talcs (and mentioned in other companys' April, 1976 comments), but it is uniquely a serious problem with samples which contain vermiculite dust. As shown in the attached photograph, platelets of vermiculite tend to impinge the filter membrane on edge. Although these vermiculite plates are totally different from asbestos, they tend to be counted as fibres unless the laboratory technician is particularly experienced in evaluating this sort of sample. Grace has experienced the same difficulty with mixed samples including dust from ingredients other than vermiculite. Gypsum is a particular problem. Grace has reevaluated samples only to find actual airborne concentrations of tremolite fibres were 1/2 to 1/3 of initially reported values. Definite particle identification is very difficult by optical microscopy for technicians experienced in vermiculite. This is a problem with vermiculite, it is most aggravated at low concentrations, and we ask this problem receive serious consideration.

In summary, Grace believes that the NIOSH/OSHA position that 0.5 f/ml (let alone 0.1 f/ml) concentrations are measurable is valid only in controlled, laboratory conditions, if there. Grace and others with years of experience in monitoring airborne concentrations under the responsibility of accurately evaluating all workplaces (not a selected few) believe a standard of 0.5 f/ml cannot be reliably measured.

D. Exposure Level (C) An entirely different perspective on lowering the exposure level--besides measuring it--is whether a reduction is justified or has a benefit. Nowhere does the proposed standard or the "Reexamination" document inadequacy of the recent 2 f/ml standard. The only available data shows that persistent exposures to commercial asbestos well above that permitted under the current standard do have an adverse effect. No data has been presented to show that the recent 2 f/ml standard is an "unsafe" exposure for commercial asbestos--let alone tremolite. Neither is there any evidence to show that a lower standard would have any improvement in employee health.

1. In our April, 1976 commentary, we requested that OSHA consider a 5 f/ml standard be implemented for Tremolite. How likely this is in the face of political pressure to treat all "asbestos" as "asbestos" may be another matter, but Grace seriously submits that the facts support such a case.

2. We again wish to draw attention to the fact that the epidemiological data cited by the government does not correlate hazards with exposure levels, and that where rudimentary exposure data was available within the studies it showed massive exposures.

3. Many of the epidemiological studies cited involve multiple exposures to harmful materials in conjunction with formidable exposures to commercial

asbestos, or, alternatively massive exposures to mixed types of commercial asbestos (as mentioned above).

4. One study that we are aware of which sought to establish dose:response relationships for commercial asbestos (Dr. P. E. Enterline, University of Pittsburgh, 1976 Industry:Government Asbestos Conference and planned for publication in Archives of Environmental Health) shows a mean 78.3 year occupational exposure latency period for lung cancer and mesothelioma at 2 f/ml, (and 124.3 years at 0.5 f/ml). In other words, based on an analysis of all epidemiological studies where approximate commercial asbestos exposures could be estimated, it was projected that the health hazard at 2 f/ml was minimal, with mortality due to other causes occurring first. The other study directed to dose:response was from OSHA (Benefits and Costs of the Federal Asbestos Standard, University of Delaware, 1975). It stated (p. 15) "...While it is unlikely that asbestos-induced diseases will be completely eliminated by a 2-fibre standard, they may be reduced to a negligible number, provided the standard is vigorously enforced. In the estimation of benefits and costs, we assume that the number of asbestos-induced diseases occurring under any 2-fibre standard will be so negligible that they can be ignored." As discussed above, there has been no new data introduced since the time of this study which could reasonably invalidate that statement.

Based upon the data available on relative characteristics of tremolite versus commercial asbestos discussed above, by comparison with these two studies, 2 f/ml (or 5 f/ml) are very conservative standards for asbestiform Tremolite.

5. Although Grace concurs with the utility of massive-dose, animal tests to clear minerals, positive results indicate need for further tests. Tremolite has shown negative results in 25 mg interpleural injections (as noted above although not mentioned by NIOSH).

6. The NIOSH Reexamination emphasizes descriptions of man's response to massive doses of commercial asbestos even though it acknowledges that a dose: response relationship does in fact exist (p. VI-1). In convoluted logic NIOSH then concludes (p. VI-2) that an absence of data showing the current exposure standard is unsafe is the reason that the exposure standard must be cut to the lowest detectable level. This is illogical besides being unreasonable for commercial asbestos. Including Tremolite in the exercise is even further afield, justification-wise.

7. The Proposal and the Reexamination based their recommendations not on health hazard data or even projections of hazards at 2 f/ml but upon the measurement method's theoretical capabilities (discussed above).

Grace states that the proposed reduction from the recent (July 1975) 2 f/ml standard is without basis.

E. Monitoring (e) The requirement that the employee be notified within 5 days after receipt of results should be modified either by addition of the words "or as practical" or by OSHA clarification. In a large employer organization, it is not practical for the employee to be notified 5 days after a laboratory technician first makes the determination.

F. Medical Requirements (j) The proposal requires annual physical examinations for all employees exposed to asbestos fibres. This is irrespective of whether the employees are exposed above, at, or below the permissible levels. Considering that someone crossing a street on his way to work is probably exposed to asbestos fibres, this is unreasonable. An action level should be adopted for the annual medical examinations requirement in the proposed standard, perhaps one-half the permissible 8 hr. TWA. An appropriate reference point would be the 1 f/ml action level adopted by California OSHA for medical examinations of employees exposed to asbestos fibre in that state (Article 5208), the California Standard being recognized by Federal OSHA as having employee health protection equivalent to the current Federal program, and thus operated with Federal funding participation.

In this connection, it should be noted that, in fact, OSHA already omits the requirement for annual medical examinations below an exposure action level of 0.1 f/ml, and has documented this policy.

The proposal's requirement for a Physician's statement that the employee has or doesn't have a medical condition which might place him at risk, or indirectly aggravate a pre-existing medical condition, is unreasonable. This requirement asks the physician to designate "no risk" situations. In today's malpractice environment, few physicians can be expected to respond to such a point. Many of our plants are in remote locations with restricted availability of medical personnel.

The Physician's Statement requirement should be deleted, and replaced with a statement of Physician's Opinion as to whether the employee has a significant medical condition which is commonly recognized as being materially impaired by exposure to asbestos.

G. Regulated Area (d) The proposal designated any area where employees may be exposed in excess of permissible levels to be a Regulated Area. Inasmuch as the standard required monitoring of all employees who may be exposed to asbestos fibre at any level, as a practical matter, employer identification of "hazard" assignments and work stations is intrinsic to the proposed standard (and the existing standard). Thus, those areas which have been found through monitoring to expose employees at or above permissible levels (or, at or above a lower, action level of one half the permissible levels) would be a better criterion for "Regulated Area."

The requirement of a daily roster is burdensome and unnecessary, either in determining an individual's exposure or in evaluating the hazards facing an employee. This requirement is, in any event, obviated by the Standard's initial and scheduled exposure monitoring requirements.

H. Labeling (l) This is an important subject to Grace. We take exception with the current standard in this section and have communicated this to OSHA before.

A fundamental tenet of employee safety programs is to reserve the "hazard" designation for a relatively few hazards, and not to identify a multitude of objects as hazardous and thus diminish the effect of the warning label. To this end, the paragraph has appropriately provided an exemption for fibres modified by a bonding agent, coating, binding or other material, where

concentration of airborne asbestos fibres is not expected to exceed designated concentrations. However, for no apparent reason, the same exemption does not apply to unmodified asbestos fibres, even though the airborne concentration of unmodified asbestos fibres would in many cases be substantially less than the airborne concentrations of fibres from a modified product. This is particularly true with respect to non-commercial minerals which occur widely as natural trace contaminants in bulk materials. Obviously, in many cases it is impossible to eliminate or to "modify" these trace minerals. However, under the proposed (and the current) labeling requirement, products containing these trace minerals would require full asbestos warning labels, no matter how small the amount released in use, transportation, etc.

We recognize that addition of a bonding agent could be an important change in a material formulation which included commercial asbestos. However, the overriding consideration must be the actual employee exposure level, not trace contamination of bulk materials. The functional criterion in regard to labeling is whether the product releases fibre and what is the nature of the hazard that is present.

As a matter of practice, it appears our views are shared by Federal OSHA. Mr. Grover Wrenn, Chief, Division of Health Standards Development, stated on September 9, 1976, at the AIA Industry-Government Conference: "The (asbestos) standard addresses itself to exposure to asbestos...The standard does not explicitly differentiate among various products containing asbestos but addresses itself to employee exposure to asbestos, and the burden then of the standard will be a function of the extent to which a particular product containing asbestos is capable of releasing that asbestos into the workplace, resulting in employee exposure" (pp. 87/88 Proceedings).

Grace is not aware of all other parties who have recommended OSHA consider this point of fibre release versus presence, but knows that they include the following, based on a review of some April, 1976 comments. Some were commenting on the Proposal's Asbestos Definition, and others on labeling, as the two are related:

- GAF recommended a change so that "'Asbestos Product' means any product made wholly or partly from asbestos where the fibre is not locked in and in use, application or handling would release airborne concentrations above permissable levels" (p.2).

- The American Mining Congress stated that "...It would include asbestos products which contained even trace amounts of any of the identified minerals which occur naturally along with many minerals which are mined" (p. 2).

- PPG Industries noted that "...The definition of asbestos includes 'every product containing any of these minerals,' however, the standard does not reveal how this is determined. The use of 'any' could be as restrictive as to mean even one fibre. Recommendation: There needs to be a lower limit of acceptable levels of these minerals in products, otherwise there is no lower limit even for inherent impurities. The Definition should be rewritten as follows: '...and every product that is likely to contain asbestos which in its use or preparation would result in exposure, to the employee, airborne levels in excess of the permissible limit.'"

- Johns Manville pointed out in their recommendations that "...It is well recognized that asbestos is a natural component of the earth's crust. Serpentine rock, which is the host rock for chrysotile asbestos fibres, is common in this country. Therefore, asbestos is ubiquitous in the soil of the United States...Serpentine rock is quarried in certain states and much of it is used in road construction (pp. F.14-15)...asbestos can be present as a constituent of certain substances and products at extremely low levels, although asbestos is not intentionally used or added. Considering the almost universal presence of asbestos in the environment, one can neven be certain that asbestos is not present, in the absolute sense, anywhere." (p. F.2)

Accordingly, we ask that the labeling language as proposed be modified as follows:

"(2) Danger labels.

(i) Labeling. Caution labels shall be affixed to all raw materials, mixtures, scrap, waste, debris, and other products containing asbestos fibers or to their containers except that no label is required in cases where during any reasonably foreseeable use, handling, storage, disposal, processing, or transportation, no airborne concentrations of asbestos fibers in excess of the exposure limits prescribed in paragraph (c) of this section will be released."

We believe that this modified language would not increase one employee's exposure to harmful fibre concentrations as defined under the Proposed Standard's paragraph (c). We believe that the modified language would prevent a serious and adverse impact on employees and employers engaged in supply and use of bulk materials and possibly other industries as well.

We believe the modified language accurately states the original intent of the Federal regulations, and that OSHA should take this opportunity to correct the obvious inconsistency and inequity in the present wording. That wording presumes the same hazard in a carload of loose bulk building material aggregate containing one fibre as in a bag of pure chrysotile.

The present labeling wording has another serious inconsistency. That is, it would trigger extensive, expensive monitoring and medical programs among myriad customers who had (inconsistently required) labeled products at their place of employment. This would occur even when the airborne exposure levels associated with those products were below detectable monitoring levels.

I. Other - Grace has identified several other aspects of the proposed standard which we believe could be materially improved by revisions. The criteria involved are practicality and costs versus safeguarding/improvement of our employees' health. However, based upon a review of industry comments filed in April, 1976, we know OSHA is aware of counterpart comments by others directed to these very points. Thus, rather than talk at length on many issues, Grace has instead elected to comment at length today on those relatively few points which are very important and/or unique to us versus the other parties testifying here.

DRAFT
4/11/77

SUMMARY

W. R. Grace & Co. summarizes our position on four key points:

1. The Asbestos Definition should be revised so as to refer to Tremolite (and other minerals) only in naturally-occurring fibrous form because there is not basis for including non-fibrous minerals.

   The definition should also be revised to include "products containing asbestos" only where those products have the potential to expose people above permissible limits. The change to define fibre as "particulate form" should be deleted.

2. The recent (July 1976) exposure levels of 2 f/ml and 10 f/ml should be retained. There is no data to show either that they constitute a relative hazard or that a lower level would be an improvement. Contrary to agency statements, the lower levels proposed are not feasible, monitoring-wise. Under no circumstances should a lower limit be considered for tremolite.

3. Medical Examinations should be required only at exposures above the permissible limits because the practical alternate end state is examination costs from all employees without any health improvements related to the Asbestos Standard.

4. The labeling requirement should be limited to those products which have the potential to expose people above permissible limits because the alternative is labeling of products posing no hazard as defined under the Asbestos Standard.