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May 30, 2007

Ms. Diane Miller
NIOSH Docket Office
Robert A. Taft Lab.
Mail Stop C-34
4676 Columbia Parkway
Cincinnati, Ohio 45226

RE: Asbestos and Other Mineral Fibers: A Roadmap for Scientific Research

Dear Ms. Miller:

The National Institute for Occupational Safety and Health (NIOSH) recently requested comments regarding the captioned draft document. This correspondence and the appended reference materials constitute a response to that request by R. T. Vanderbilt Company, Inc. (RTV).

NIOSH states that in the mid to late 20th century advances were made in the understanding of asbestos fiber risks. It further states that while asbestos risk is well documented, other elongated (minimum length to width ratio of 3 to 1) or "fibrous" particulates are not well understood and remain controversial. NIOSH now seeks to clarify these issues and establish an improved fiber risk policy.

RTV recognizes the exceptional contribution NIOSH has made to the health and safety of workers. In respect to fiber risk, however, it is our belief that NIOSH has itself contributed too much of the confusion described in the draft Roadmap. Further, we believe several issues outlined in this draft document are better understood than NIOSH suggests. RTV feels this is particularly true in regard to elongated nonasbestiform amphiboles (cleavage fragments), which this submission will principally address.

Tremolitic talc, now mined and milled exclusively by R. T. Vanderbilt Company in upstate New York, has played a prominent role in the understanding of amphibole cleavage fragments for decades. The company's talc miners and millers are likely the most exposed work population to amphibole cleavage fragments in the world.

An updated technical overview entitled "Asbestos, Health Risks and Tremolitic Talc" (White Paper) is appended. This overview provides a relatively complete account of our experience and understanding of this matter. RTV's submission to NIOSH consists of this White Paper, a series of topic files that contain most of the documents referenced in the White Paper, and additional

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comments on specific statements and issues raised in the draft Roadmap that we feel are misleading and/or inaccurate. For more detailed discussion on assorted topics the White Paper will be periodically referenced throughout this submission. We hope the appended materials are helpful.

Concern

Since NIOSH currently maintains a policy that treats elongated nonasbestiform amphiboles and serpentine minerals as posing a "same as asbestos" risk, statements appear in the draft Roadmap that warrant comment beyond that found in the appended White Paper.

One such statement appears on page 9 of the document in regard to cleavage fragments: ***"a conclusion that exposure to fiber-like cleavage fragments does not cause cancer lacks certainty due to the limited quality of relevant human health and animal data."*** Much of what follows speaks directly to concern over this assertion.

Vanderbilt Talc:

Human **exposure** to elongated nonasbestiform cleavage fragments in worker health studies is generally unclear in the literature as NIOSH suggests. In respect to RTV talc, however, this is not the case. While overall dust levels are significantly lower at the RTV mine than those experienced decades earlier in other area talc mines (lower by a factor of 10 or more), elongated cleavage fragments are present in the Vanderbilt work environment at levels well in excess of the current OSHA permissible exposure limit for asbestos fibers. According to NIOSH fiber counting criteria (NIOSH PCM Method 7400), the average RTV mine and mill exposure to elongated amphibole cleavage fragments ranges from 0.5 to over 1.0 fibers per cubic centimeter of air over an 8 hour TWA (excluding other elongated components such as talc fiber). This exposure is a minimum of 5 to 10 times the current OSHA PEL for asbestos, and would be a significant exposure if these amphibole fragments did, in fact, pose the same health risk as asbestos.

FILE 1 contains documents that detail the composition and prevalence of elongated amphibole cleavage fragments in bulk RTV talc as well as in airborne exposure in the mining and milling environment. Information pertaining to general dust levels at other regional mines operated in the past is included as well. Vanderbilt talc is one of the most studied mineral products in the world and as such has undergone extensive characterization in terms of exposure levels, particle sizing and mineralogy.

Researchers who believe the risk of elongated amphibole cleavage fragments is in part "unclear" because exposure information is lacking, or because exposure levels are too small to produce a biological response, are encouraged to consult the documents in File 1.

The biological **response** associated with this amphibole cleavage fragment exposure has received as much attention as the mineral composition of the talc itself. RTV talc has been the subject of half a dozen mortality studies, several morbidity studies, two animal studies and one cell study. **FILE 2** contains a copy of each of these studies in chronological order, with attendant critiques. With the exception of the cell study, each study addresses the issue of nonasbestiform amphibole risk.

A few non-RTV talc health studies also exist that address mining in the same general region. These other studies, however, involve particulate exposures that are not well characterized (if at all), and mining operations that no longer exist. RTV would describe these studies as lacking "certainty" and questions their relevance to existing exposures.

An excess lung cancer rate among RTV talc workers is observed in each mortality study, as the Roadmap points out. Strong evidence, however, points away from the dust exposure (whatever its composition) as the cause. In the draft Roadmap, NIOSH however describes the lung cancer deaths as **"not clear"** as to whether they are **"work-related".** The health studies contained in File 2 speak for themselves and deserve a careful, thorough review.

While an extended discussion of RTV talc health studies can also be found in the appended White Paper, a few key observations from these studies appear below. Several of these observations were not mentioned in the draft Roadmap even though NIOSH had been provided this information in January of 2004, and it can also be found in the published literature.

Vanderbilt Talc Health Study Highlights and Roadmap Omissions:

The draft Roadmap points out that every mortality study of RTV talc workers suffers from a small study population. Although true, this weakness is less pronounced in larger, more recent studies. The original NIOSH Technical Report (1980) involved a cohort of 398 workers spanning 29 years. The most up-to-date mortality study (Honda, et al 2002) involved 809 workers and spanned 41 years. Most importantly, a number of key causal observations have been made over the years that were not adequately addressed, or omitted altogether, in the draft Roadmap.

- An inverse dose response was clearly demonstrated with regard to RTV talc exposure and the lung cancer observed by both tenure and cumulative respirable dust. The authors of the Honda, et al study accordingly concluded that "because internal analysis should be minimally subject to confounding by non-occupational exposures, the absence of a positive dose-response pattern ***does not support*** the hypothesis that the talc ore of the plant per se is a lung carcinogen." (emphasis added). In the NIOSH Roadmap this study is referred to as the "most thorough" mortality analysis of RTV talc workers.

- A comparison with another talc mining operation whose ore does not contain amphibole cleavage fragments (Vermont talc workers), shows no difference in the lung cancer rate for workers with more than 1 year of exposure. (File 2 - Lamm, et al 1988).

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Interestingly, mortality linked to nonmalignant respiratory disease appears higher among talc workers in Vermont, who are **not** exposed to nonasbestiform amphibole cleavage fragments.

- The smoking history of RTV talc workers has been addressed and appears to be at least twice as high as that of the US male population. NIOSH described smoking information in the draft Roadmap as "very limited". In a case control study cited in the draft Roadmap but not discussed (File 2 - Gamble 1993), smoking was specifically addressed and described as the most plausible explanation for the lung cancers observed. Not only had all the lung cancer cases been smokers but 73% of the study controls were current or past smokers. A review of RTV's pulmonary function questionnaires dating back some 25 years (see page 13 of the appended White Paper), suggests a smoking prevalence of approximately twice the national average for US males over this time span. While some argue that smoking can not account for all the excess lung cancer observed, others feel that it can (i.e., within the confidence interval of the mortality study). To describe smoking information as "very limited" in the case of RTV talc workers is misleading.

- The recent pulmonary status of RTV talc workers has been shared with NIOSH but was not mentioned in the Roadmap (this information appears in File 2 and is discussed in the White Paper, pp 19-23). Experienced miners who were previously exposed to very high dust levels in other area talc mines were hired at the RTV mine. (The last competing area talc mine closed in 1974.) As these experienced miners have left the employment of RTV (typically through retirement), a much higher percentage of miners who have only had exposure at the RTV mine remain, and the pneumoconiosis cases previously observed among RTV talc workers has dramatically decreased. Routine medical surveillance no longer reflects elevated pneumoconiosis among RTV talc workers. Today, approximately 60% of the talc workers have been employed in excess of 20 years, with the vast majority now having exposure only to talc from the RTV mine and mill. In 2002 only one miner showed "possible irregular opacities (ILO Classification of profusion of 1/0) which had not changed since 1994" after 31 years of exposure. The total number of talc workers reviewed numbered 115.

  Pleural plaques were observed in some workers with more than 15 years exposure (6 confirmed in total or approx. 5%). This finding is consistent with other talc worker populations without exposure to nonasbestiform amphiboles (File 2 - B. Boehlecke pulmonary status overview 2002, and appended NIOSH studies of Montana, Texas and North Carolina). Given these observations, pleural plaques and pleural thickening do not appear to be an exclusive signpost of asbestos exposure, nor do they appear related to nonasbestiform amphiboles. It is RTV's understanding that pleural plaques are considered to be abnormalities and not a disease (unless extensive and impacting lung function), and are generally not felt to predispose workers to pulmonary cancer.

  The company's medical consultant (a former NIOSH pulmonary division head and Professor of Medicine at the University of North Carolina) concluded that "the data do not indicate that the workers exposed to the talc at this facility are at risk for developing asbestos-related pneumoconiosis." The results of more recent pulmonary evaluations continue to reflect this experience. RTV believes that this pulmonary experience may well be among the best in mining, and that it is not "unclear" or "equivocal". We would be happy to once again share these findings with NIOSH and establish a dialogue between NIOSH and our medical consultant. NIOSH declined the opportunity in 2004.

- Two separate animal studies tested RTV talc, as well as a concentrate of tremolite from the talc, against asbestos at different dose levels in rodents (File 2 – M. Stanton, et al 1981, Smith, et al 1979, see also White Paper pp 15-16). In both studies, RTV's talc (and the tremolite concentrate) produced zero pleural tumors, as opposed to the asbestos samples tested under the same conditions. The draft Roadmap does not address these studies of RTV talc, although they have been provided to NIOSH in the past.

Since the animal studies and their link to RTV talc and amphibole cleavage fragments were not mentioned in the draft Roadmap, further discussion of these studies appears warranted. They involved injection and implantation of RTV talc in the pleura of two animal rodent models (rats and hamsters). Though issues of experiment duration (rodent life spans) and dose might be raised, **zero** tumors were observed with RTV talc (whole product) as well as with RTV nonasbestiform tremolite tested separately, while tumors were recorded from asbestos tested at equal dosages and testing duration. No "same as" effect was demonstrated.

It is our understanding that animal researchers view the direct application of substances on the pleura as an extremely sensitive test, one more prone to false positives than false negatives. RTV further understands that there is typically little support for testing substances in inhalation studies when tumors are not produced in exceptionally sensitive studies of this nature.

The RTV talc samples used in both studies have been fully characterized and described in several publications (File 2 - Wylie, et al 1993; Lee 1990). The evaluation of future research needs outlined in section 2 of the draft Roadmap can be adversely influenced by such omissions. For example, the need for a rodent inhalation study for elongated amphibole cleavage fragments may not be necessary given the negative results of the pleural injection/implantation studies involving the same material.

Interestingly, the work of Dr. Stanton is often referenced in support of fiber dimension as the only fiber characteristic worthy of consideration. This work is often cited as the foundation upon which to build a "one size fits all" generic fiber risk policy. Dr. Stanton's landmark work, however, shows some contradiction in sample results that suggests that mineral type plays an important role as well (to be discussed later in respect to talc fibers – "Asbestiform crystal growth" section). Additional review of Dr. Stanton's work can be found in File 2 (see Oehlert 1991).

The last document in File 2 is an overview of RTV talc health studies by G. Gibbs (2004). It is provided as a second summary reference.

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Mesothelioma and RTV Talc:

Mesothelioma has not been reasonably linked to RTV talc exposure. The qualifying phrase "reasonably linked" must be used because mesothelioma has been reported on the death certificates of former RTV talc workers.

Two mesothelioma deaths were reported in the published mortality studies but were not linked to RTV talc dust exposure by the investigators. The most recent study covered a span of 41 years. Insufficient latency in one case, and a significant confounding asbestos exposure in the other (several decades of furnace repair and removal), suggest that talc was not the cause. Neither animal study involving direct pleural implantation and injection (File 2 - Stanton and Smith) nor the cell study involving pleural mesothelial cells (File 2 - Wylie, Mossman, et al 1997) lend support to a mesothelioma link. Also, the fiber sizes most associated with mesothelioma are very rare in RTV talc. The elongated particles found in RTV talc that most closely approximate the size of asbestos fibers are talc fibers, not amphibole cleavage fragments. Talc fiber will be addressed in a subsequent section.

Since the vital status cut-off in the last mortality study at the end of 1989, several additional mesothelioma deaths have been reported through the Workers' Compensation system. These claims were investigated in respect to work histories and diagnostic reliability by physicians experienced in mesothelioma diagnosis. Tissue analysis, when available, was performed.

Investigation suggests that these cases fell into one of two categories: those likely diagnosed incorrectly or those correctly diagnosed but showing evidence of exposure to actual asbestos. In two cases exposure to actual asbestos occurred at the RTV mine as a result of working with and around insulation materials and machine brake pads, as well as asbestos exposure in other employment. Recognizing the importance placed on this rare cancer and its close link to asbestos (though differences of opinion exist on how closely it is linked), **FILE 3** contains more detailed information on the reported cases (names blacked out).

Included in File 3 as well is a mesothelioma case review published in 2002 as a supplement paper (Hull, et al 2002). Although it is a case comparison study with no specific or clear link to RTV talc, this paper does "suggest" a causal link between exposure to talc mined in the upstate New York talc mining region, various mineral components found in the lung tissues examined (elongated cleavage fragments among them), and mesothelioma. This study underwent a formal review by mineral scientists, pathologists, epidemiologists and a risk analyst, who found the document seriously lacking in a variety of areas. Critiques of this paper are included in File 3.

RTV Talc: Summary Statement

Because RTV talc is the most studied exposure to amphibole cleavage fragments, it is important to objectively and fully review the mineralogy, exposure levels and demonstrated health risk associated with this unique talc. RTV believes the information currently available is of such a quality and quantity that it is misleading to describe it as unclear or "lacking certainty" when all the study results consistently point away from a causal link between RTV talc and lung cancer. Although this talc contains other minerals besides nonasbestiform amphiboles, the absence of an asbestos health risk does not support a "same as" risk for nonasbestiform amphiboles.

Non-Vanderbilt Health Studies and Nonasbestiform Amphiboles:

FILE 4 contains non-RTV health studies that also involve exposure to nonasbestiform amphibole cleavage fragments. Like the RTV talc worker studies, these human cohort studies also involve mixed mineral dust exposures. However, unlike the RTV talc worker studies, the amphibole exposures involved (predominantly cummingtonite-grunerite) are not well characterized in regard to exposure levels or particle sizes. However, to the extent these human, animal and cell studies include exposure to nonasbestiform amphiboles and do not demonstrate a "same as" health effect, they lend no more support to a "same as" asbestos policy for cleavage fragments than RTV talc studies do. The Homestake and Reserve Mining studies are viewed as the two most significant human cohort studies. Both involved large mining cohorts with follow-up collaborative study (see appended White Paper, pp 18-19, for additional discussion).

In regard to non-RTV talc animal studies, it is interesting that the draft Roadmap makes special reference to a rat intraperitoneal injection study by Davis, et al (1991). It points out that three nonasbestiform tremolite samples of different morphologies produced late hour tumors, with one of the three producing a significant number (the Italian sample). Three tremolite asbestos samples, in contrast, all produced significant early tumors.

The authors of the study point out that the study design is highly sensitive to tumor induction and that "it is usually considered that, with a 10 mg dose, any dust that produces tumors in fewer than 10% of the experimental group is unlikely to show evidence of carcinogenicity following administration by the more natural route of inhalation." The occurrence of a relatively few late hour tumors in two of the three nonasbestiform tremolite samples would, the authors conclude, "most certainly" or "probably" be considered "harmless to human beings" (File 4 - see Discussion section of the Davis, et al study). NIOSH simply describes this observation as "uncertain".

The acicular or byssolitic nonasbestiform Italian sample was found to contain a small subpopulation of asbestiform tremolite, which was noted in the study but not clearly referenced in the draft Roadmap. Instead of noting that this sample suggests the potency of a small exposure to amphibole asbestos, the Roadmap suggests that the higher aspect ratio cleavage fragments might have been the cause (page 10 of the draft Roadmap). The late hour tumors observed with the Italian sample would seem fully consistent with what might be expected from a minor asbestos exposure.

In its brief discussion of this animal study NIOSH obscures the authors' conclusions and does not adequately address the implications of the Italian sample.

FILE 5 contains several reviews of all known nonasbestiform amphibole health studies (human, animal and cell) prepared by mineral scientists, epidemiologists, pathologists, and physicians who have published on matters pertaining to asbestos and fiber risk in general. All have many years of direct experience in the field and several have published extensively on the subject.

One review principally focuses on animal studies (J. Addison and E. McConnell 2006), and provides a more detailed discussion of the Davis/Addison study mentioned above (pp. 18 – 21 of this overview). Reviewers are encouraged to carefully consider these documents.

Nonasbestiform Amphiboles and OSHA:

As the Roadmap document notes, nonasbestiform anthophyllite, tremolite and actinolite were addressed by OSHA 17 years ago. That regulatory undertaking included an extensive review of the pertinent health and mineral science literature available at the time. In the draft Roadmap, NIOSH does reference the regulatory conclusion OSHA reached: "current evidence is not sufficiently adequate for OSHA to conclude that these mineral types pose a risk similar in magnitude or type to asbestos". In respect to the current reincarnation of this matter, interested parties are strongly encouraged to review the public record submissions and testimony associated with that rulemaking (OSHA Docket No. H-033-d).

RTV believes that much of the OSHA rulemaking record is as relevant today as it was in 1990. In fact, we believe the evidence supporting OSHA's decision not to treat nonasbestiform amphiboles as a "same as" asbestos risk is stronger now (see summary reviews in File 4 and the appended White Paper). OSHA reached this conclusion after first indicating its intent to act otherwise. That OSHA reversed its position in 1992 after a more complete review of the matter suggests that there was a reason.

Then as now, RTV is not aware of a single human, animal or cell study that involves exposure to elongated amphibole cleavage fragments (absent an asbestos co-exposure), that shows a "same as" asbestos health effect. In the draft Roadmap, however, the health effects associated with exposure to nonasbestiform amphiboles are repeatedly described as unclear and ***"lacking certainty"***. To relive this issue again is unfortunate and, we believe, completely unnecessary.

The NIOSH Position on Nonasbestiform Amphiboles:

The failed argument NIOSH made in 1990 that OSHA should treat elongated nonasbestiform amphiboles and serpentine minerals (i.e., antigorite) in the same way as asbestos is repeated in the draft Roadmap. NIOSH described the health effects of cleavage fragments as equivocal in regard to human studies and dependent on dimension and durability in respect to animal studies. As a result, NIOSH made no effort to properly identify asbestos and maintains to this day imprecise, overly broad analytical fiber counting protocols (Methods 7400 and 7402). As NIOSH correctly points out, neither method provides sufficient guidance to reliably differentiate elongated cleavage fragments from asbestos fibers. Yet these methods are used almost exclusively for asbestos because there are few other fiber standards for which they would be used.

As noted above, there are no known animal studies involving amphibole cleavage fragments of any dimension that show a "same as" asbestos risk. The general statement that fiber risk is related solely to size and biopersistence is not fully supported (see section on "Appropriately - Sized Cleavage Fragments" below). Even if this were true, the "sizes" most implicated in asbestos-related disease are not those of cleavage fragments, nor those used to count "fibers" in NIOSH Methods 7400 and 7402 (beyond, perhaps, the 5 micrometer length requirement).

NIOSH's argument regarding human studies is seriously misleading as well (as detailed in the appended White Paper and Files 2 and 5). NIOSH did not complete a credible mortality study of RTV talc workers, did not characterize RTV talc mineral exposure correctly, did not objectively consider critiques of its work and appeared more intent on proving a fiber policy than testing it. Other human studies involving amphibole cleavage fragments are negative for pulmonary cancer.

RTV believes the risk of elongated cleavage fragments is not ***"lacking certainty"*** because there is simply no evidence that it poses a "same as" asbestos risk. If achieving certainty requires proving a negative, this matter will never be resolved. Based on NIOSH's statements to OSHA in 1990, it appears that no corrective actions will be taken by NIOSH as long as it maintains this "lacking certainty" view.

Arguments Used to Treat Elongated Particulate as Asbestos:

The only arguments for treating nonasbestiform amphiboles (and other durable elongated particulates) as asbestos appear linked more to theory and extrapolation than study results. The following captions and discussion highlight our understanding and critique of these arguments.

Elongated Cleavage Fragments are Rare:

There is a suggestion in the draft Roadmap that the issue of nonasbestiform amphiboles might be trivial because few cleavage fragments satisfy the current fiber counting criteria for asbestos. Although it is true that few cleavage fragments do satisfy the current counting criteria (3 to 1 or greater aspect ratio, 5 micrometers or longer length), especially if a width cut-off of 3 micrometers is applied), it is RTV's experience that a good number will satisfy these arbitrary dimensions (see File 1 and section on "Appropriately-Sized Cleavage Fragments" below).

Nonasbestiform amphiboles are common rock and soil forming minerals found in roughly one third of the surface land mass of the continental United States (see USGS and BOM maps, roughly approximated on page 7 of the appended White Paper). Nonasbestiform amphiboles are used extensively in a variety of construction related applications and depending upon how this material is processed and used, will certainly contain some elongated fragments.

In respect to asbestos tort litigation in the United States it is important to bear in mind that there is no trivial or safe amount of asbestos exposure. As absurd as it may seem, a single report, claiming the finding of a single asbestos fiber (real or improperly identified) is enough to sustain litigation. Asbestos litigation in the United States has bankrupted over 50 companies thus far and frivolous claims divert attention and resources from real risks. It is very important that substances that do not contain asbestos not be described asbestos-containing. If there is any doubt that the plaintiffs' bar uses government agency positions in order to support litigation without regard to the soundness of the science, NIOSH need only look to the input of the plaintiffs' bar during the NIOSH public meeting on May 4, 2007 on this very matter.

The Lung Never Read a Textbook on Mineralogy:

It has been observed in the past that the "lung never read a textbook on mineralogy". Most health experts would agree, however, that the lung does "read" particle surfaces and the presence of long, thin fibers as it strives to digest, move or otherwise clear them.

In the draft Roadmap NIOSH recognizes that nonasbestiform single crystal fragments do not present the same properties and clearance requirements once in the lung as does a similarly sized asbestiform fiber entering the airway (page 10-11). In effect, while a cleavage fragment and an asbestos fiber of the same length and width might enter the airway, once in the lung they do not remain "the same".

As NIOSH notes, asbestos fiber bundles will separate or disaggregate in the lung along their length axis, yielding thinner and thinner fibers of the same length. The lung must then clear an increasing number of thin fibers with a vastly higher surface area than that of a single crystal cleavage fragment (File 4 - Cook, et al 1982). How the lung reacts to these structurally different particulates is not and can not be "the same". The lung doesn't read textbooks, but it certainly does read the mineralogy of particulates.

Researchers that dismiss this unique asbestiform growth habit in favor of *exclusive* focus on particle lengths and widths do little to advance the understanding of asbestos fiber risk. Worse still, failure to understand this unique crystal growth impedes the proper identification of asbestos and is the root cause of imprecise analytical criteria in the identification and quantification of asbestos.

RTV feels strongly that proper particulate identification is crucial regardless of risk (real or imagined). We believe agreement on this principle must be reached before any progress can be made in this area. Underestimating the risk of true asbestos through the dilution of such exposures with non-asbestos particulates, for example, is not in anyone's best interest. In File 6 (see below), one example of exposure dilution due to imprecise mineral identification can be found (Wylie & Bailey 1992).

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There is little indication in the draft Roadmap document that crystal growth habit is viewed as both an important risk factor and analytical consideration. The unique asbestiform crystal growth habit separates asbestos from non-asbestos more emphatically then any other characteristic. This growth structure is, in fact, the hallmark of asbestos. Analytical protocols designed to identify asbestos should not ignore this hallmark characteristic and focus exclusively on particle dimension if the protocol hopes to be asbestos-specific. The recognition of this growth habit with regard to individual fibers and populations of fibers is, in our view, significantly more important than measuring particle lengths and widths.

"Appropriately-Sized" Cleavage Fragments:

Expanding upon the prior discussion, NIOSH continues to suggest that particle size and biopersistence "alone" are all that matter from a fiber risk perspective. This then supports the notion that "similarly sized" particles of the same mineral (regardless of crystal growth habit) "should" or "ought" to pose the same risk. Though seemingly reasonable on its face and supported by the fact that particle durability and dimension do play a significant role in fiber risk, research suggests that the biological impact of asbestos and other fiber induced disease is not this simple.

Mineral scientists who have studied cleavage fragments and asbestos fiber populations tell us that not only are there fundamental differences in crystal growth habit with attendant differences in physical properties (many described in the draft Roadmap), but that elongated cleavage fragments are thick, relatively short single crystal structures. Asbestos fibers, in contrast, exhibit widths independent of lengths and are generally very thin (unless a thick bundle). **FILE 6** contains a sampling of papers that address dimensional characteristics of cleavage fragments and asbestos fibers in bulk material, lung tissue and in the air. A number of these papers discuss the risk associations relative to these size dimensions and also address the mineralogical characteristics of asbestos. More information exists in this area but we RTV feels that the enclosed papers are among the most complete.

As suggested in this literature, the vast majority (if not all) cleavage fragments longer than 5 micrometers can be seen under the light microscope. In contrast, a single asbestos fiber crystal (a fibril) is exceptionally thin and very, very few (if any) can be observed under the light microscope. Asbestos fibers that are seen under the light microscope and any that might approximate the size of an elongated cleavage fragment are therefore composed of "bundles" of fibrils and identifiable as such.

As the draft Roadmap correctly states, aspect ratios have no risk significance. Further, if one attempts to treat "appropriately sized" cleavage fragments as or like asbestos, the first question must be the definition of "appropriately sized". For most, appropriately-sized simply means the arbitrary fiber counting criteria presently employed to count asbestos fibers by light microscopy. Some laboratories, however, use the counting criteria to also define asbestos (directly contradicting expressed regulatory intentions) and in so doing mischaracterize the exposure,

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improperly infer risk, spuriously promote litigation and misdirect scarce resources (File 6 – Millette 2006, is an example of improper use).

All nonasbestiform amphibole cleavage fragments with lengths greater than 5 micrometers can be seen under the light microscope. In stark contrast, most asbestos fibers can not be seen under the light microscope though this will vary by mineral type and degree of fiber breakdown. As NIOSH points out, the use of light microscopy for asbestos fibers provides only an "index" of asbestos fiber prevalence.

For this reason, efforts to equate an asbestos fiber concentration to an elongated cleavage fragment concentration based on light microscopy fiber counting criteria is not possible. Counting all cleavage fragments that meet the counting criteria while missing most asbestos fibers with the same analytical technique is akin to comparing apples and gold fish. Unless it is felt cleavage fragments should be regulated more stringently than actual asbestos, it is important to bear this disparity in mind.

Along these lines, if fiber size is to be used in analytical protocols to the exclusion of all other characteristics, then the dimensions of asbestos fibers most associated with adverse health effects should be employed to better separate asbestos fibers from nonasbestiform elongated particles. RTV believes the totality of research in this area consistently points to long (in excess of 10 micrometers) thin fibers (less than 0.5 micrometers) as most associated with asbestos cancer risk. Variations in fiber size have been reported depending on the asbestos disease end point and asbestos type (File 6 - Lippmann/Timbrell 1990; Berman et al 1995).

The sizes of fibers most implicated in asbestos disease are not similar to the size of cleavage fragments. On an individual fiber basis there may be a few that are similarly sized – but the fibrillar bundling of the asbestos fiber in those instances should be apparent, as discussed above. Particle population characteristics are also critical in making the proper distinction. Moreover, even if a change in size criteria were adopted, proper asbestos identification is still not ensured. Only when accurate mineralogical criteria are incorporated into analytical criteria can this distinction be reliably accomplished. However, an adjusted fiber size counting criterion more in keeping with current risk knowledge would seem wise.

We believe there is value in adjusting the fiber counting criteria to dimensions more typical of asbestos fibers through a light microscopy screening technique such the ASTM and NSSGA approaches noted in the draft Roadmap. Size parameters would need to recognize as many true asbestos fibers as possible, while avoiding the counting of cleavage fragments (File 6 - Harper & Lee 2007). Recognition of the unique fibrillar growth habit of asbestos (asbestiform habit) should always be considered in such methods as well. Such an adjustment would be particularly useful in complex or mixed dust environments such as those found in the mining industry and in areas involving what is referred to as "naturally occurring" asbestos.

Of course the limitations of these screening approaches must also be understood and more rigorous analysis applied when there is a question as to the nature of the elongated particles. It is often argued, however, that to abandon the current fiber counting scheme would jeopardize the historical risk database. RTV believes that such an adjustment would not jeopardize this database because actual asbestos would continue to be counted as it was in prior sampling involving asbestos. Use of the existing counting criteria as a first pass would also reduce this concern. In this case the analyst would not move to a more discriminating fiber count unless the original counting criteria exceeded a certain level. The advantage of this approach is that far fewer elongated cleavage fragments would be confused with asbestos, and time and resources would be saved.

Asbestos Standard Materials:

Recognizing that nonasbestiform elongated cleavage fragments must be separated from asbestos fibers for regulatory purposes, asbestos standard materials such as those provided by NIST and UICC are used by analytical laboratories to assist in making the necessary distinction. Not commonly understood, however, is the fact that asbestos material standards are not composed entirely of asbestos fibers. Elongated cleavage fragments in varying amounts are seen in many, if not all, the asbestos standard materials. In some cases, the amount of cleavage fragment material is substantial.

For laboratories with mineral science expertise, asbestos standard materials that contain nonasbestiform particles are often not a problem. In that instance the standard provides an opportunity to compare morphological differences in order to more accurately characterize the samples being analyzed. For laboratories with inadequate mineral science expertise, however, the use of mixed standards poses a problem. The presence of cleavage material in asbestos standard materials suggests to some that these cleavage fragments are asbestos fibers when in fact they are not. Obviously, nonasbestiform cleavage fragments are cleavage fragments regardless of where they might appear. **FILE 7** contains articles that address the impurity of asbestos standard materials. Note for example in an article by Brown, et al (2003), that the NIST tremolite asbestos standard (1867a) is said to contain only 19% asbestos based on morphology. Non-asbestos in this asbestos standard is again noted by Lee (2006). In a discussion of the UICC anthophyllite asbestos standard by Bowes, et al (1997), the standard is said to contain "as little as 60% anthophyllite". The Certificate of Analysis for the NIST Standard Reference Material 1867a does suggest that this standard is not pure asbestos (the sample's origin is from a mine grade asbestos material – all mine grade asbestos will include nonasbestiform fragments). In fact, it is stated in the Certificate that "the optical properties leading to certification *(as tremolite)* were measured from the larger, single crystal fibers present in the samples."

Linked to this problem is a belief that there exists a significant "cross-over" of similarly sized asbestos fibers and cleavage fragments. Nonasbestiform elongated particles, including byssolitic materials, are commonly found in asbestos mine deposits. The reverse, asbestos in non-asbestos mine deposits, rarely occurs.. When the morphology, size and optical properties (i.e. extinction angle) of these nonasbestiform particles are observed in the asbestos standard materials and compared against similar particles found in environmental or workplace samples, misidentification is quite possible (if not probable).

It is believed that some of the original asbestos fiber sizing tables published by the Bureau of Mines in the mid-1970s included the measurement of cleavage materials found in asbestos standard materials (File 6 - BOM IC 8751, page 44, figure 41). The "gray area" or "cross-over" is much smaller when non-asbestos particles are properly identified and separated from asbestos fibers. One worthwhile research project might be to obtain pure asbestos (for each asbestiform amphibole) and pure cleavage fragment material of the same mineral (of varying morphologies), and size these particulate populations for actual cross-over (if any). Pure asbestos samples are hard to find and despite similar efforts in the past, further additions to the science base in this area would be helpful. The more reliable the data in this area, the more reliable the size criteria used in PCM screening techniques (discussed above) might be.

Short Fiber:

There are numerous observations by toxicologists and pathologists who suggest that short fibers (particles less than 5 micrometers in length) might pose the same risk as long asbestos fibers, if bio-persistent. The draft Roadmap references the comments of Dr. Dodson in this regard. Researchers find more short asbestos fibers in human tissue than long fibers, yet, as NIOSH correctly points out, this does not necessarily imply causality. As repeatedly noted, long fibers (while few compared to short fibers), are most implicated in the carcinogenic effect of asbestos (as are thin widths). RTV does not believe that short fiber risk is adequately supported by animal and cell studies. **FILE 8** contains a copy of an ASTDR-sponsored expert panel review that addressed fiber length. The conclusions of the panel supports this view.

Lung clearance mechanisms do not argue for an "as bad as" asbestos link in regard to short fiber. There has been some discussion as to whether short fiber asbestos (shorter than 5 micrometers) acts differently from a pulmonary risk standpoint than any other durable non-fibrous mineral particle in regard to pneumoconiosis potential.

"Asbestiform" crystal growth = Asbestos:

It is confusing to hear that a fiber may be "asbestiform" (meaning "like asbestos") but not asbestos. It does sound like a contradiction since, as discussed above, this rare crystal growth habit is the hallmark of asbestos. Still, while all asbestos is asbestiform, all minerals that can occur in an asbestiform growth habit are not asbestos. Asbestos is a commercial term that applies to six specific minerals that exhibit this unique crystal growth habit (File 6 – Steel, Wylie, Zoltai, Campbell and others) as NIOSH correctly points out in the Roadmap document.

Mineral science texts list upwards of 100 different minerals that can occur in the asbestiform growth habit. Some of these minerals pose a risk similar in magnitude to that of asbestos (e.g. the amphibole minerals winchite and richterite and fibrous erionite – a zeolite). This is also recognized in the NIOSH Roadmap. Other minerals that can occur in the asbestiform growth habit have not been recognized as posing the same risk as asbestos. Several minerals that can be found in the asbestiform habit are actually water soluble.

RTV is sensitive to this distinction because a small but easily identifiable component in RTV talc is talc fiber. These are true fibers, not the platy form of talc that is more commonly found. Further, these "talc fibers" can be found in several fibrous forms: rod-like, ribbon-like and asbestiform.

To further complicate the matter, some of these talc fibers are "transitional". They are a combination of talc and an amphibole in a transitional phase. These particles are changing (transitioning) from one mineral to another and are intermixed at the lattice level. The mineral phases can not be separated and the particles present different properties then either of their individual mineral components. These rare fibers have been called academic curiosities and are often mischaracterized as either pure talc or pure end member amphibole (most often anthophyllite). The proper characterization of these fibers has been the subject of several highly detailed studies. The risk of these fibers has been tested as they are included both in the whole RTV talc product and in the fiber concentrate (see White Paper, pp. 24-30).

It has been suggested by some that talc fibers pose a "same as" asbestos health risk. To explain why this risk is not apparent among RTV talc workers and does not produce tumors in the animal studies, they contend it is because there are too few of these fibers in the talc. Though these fibers are a very minor component in RTV talc, we know of no higher exposure to talc fiber. It can therefore be argued that concern is not warranted.

As a unique material, however, talc fiber was important to test as a concentrate to see if it did act biologically the same as asbestos, as prevailing fiber risk theories suggest it should. Accordingly, a talc fiber concentrate was prepared and matched as closely as possible with an asbestos sample for testing (surface area, size and number of fibers per unit weight, etc.). The risk testing of these samples involved an *in vivo* cell study employing rodent tracheal epithelial and pleural mesothelial cells. The results showed that a marked difference did exist in respect to cell proliferative effects (an indicator of carcinogenicity).

For review convenience, **File 9** contains documents specific to talc fiber in all its forms. Several of these documents may be found in other file folders, while others (those that address analytical characterization issues associated with these fibers) appear only in this file.

The results of this cell study (Wylie, Mossman, et al), coupled with those of the negative animal studies, argue for the importance of mineral species as a crucial determinant in fiber risk. Talc fibers were present at a level that should have produced significant numbers of tumors in the animal studies (see Files 9 & 2 - log number of critical dimension fibers for talc sample 6 in the Stanton study).

The bio-persistence of talc fibers is not presently known but they are thought to be very bio-persistent. Determining the bio-persistence of talc fibers in their varying forms might be a valid future research project. Differences do exist between amphibole asbestos and talc fiber in respect to particle harshness and population widths. Widths tend to be wider for talc fiber: compare the size distribution tables in the Wylie, Mossman cell study. Other physiochemical properties unique to talc fiber also exist, but all the differences between talc fiber and asbestos are not presently known (e.g. biopersistence).

Beyond the issue of risk, talc/amphibole transitional particles pose a number of unique analytical challenges for which there are few existing analytical protocols. Those that do exist are by and large academic constructs that are not readily known or available to most contract laboratories. Some analytical tools such as electron microscopes were not able to recognize these unusual fibers as little as 20 years ago, assuming that analysts were aware that such diversity in mineral fiber existed in the first place. One of the research challenges, beyond improved analytical tools for the proper identification of cleavage fragments, is improved knowledge of mineralogy, meaningful comparative sample materials and broader analytical guidance for contract laboratories. It would be helpful if the complexities of mineral science were better appreciated.

CONCLUSIONS

Based upon our understanding of the issues, RTV concludes as follows:

1. Biological testing of nonasbestiform cleavage fragments (all sizes) consistently shows a marked difference in biological effect as compared to asbestos. The existing health science base in this area (human, animal and cell) is considered sufficient and NIOSH should abandon its present "same as" asbestos policy.

2. NIOSH should devote research funds to improved analytical guidance designed to reliably distinguish asbestos from non-asbestos. Further blurring this distinction should be avoided to better ensure consistency in the regulation of asbestos.

3. NIOSH could contribute to the understanding of asbestos risk by further addressing the similarities and differences between similarly sized fibers with different biological effects. This will require a more discriminating definition of "similar" and more attention to crystal structure, in vitro fate (e.g., disaggregation of fibrils), bio-persistence, surface area and activity, and other physio-chemical properties. This information, coupled with that which already exists, can be used to further refine definitions, improve analytical criteria and more appropriately predict risk.

4. Until improvements in definitions and analytical protocols are made, the best available mineralogical definitions and guidance should be used. Page 7 in the appended White Paper reflects a mineral science-based consensus definition of asbestos that is already applied, in whole or in part, in a variety of standards. Similarly, presently available analytical methodology that comes closest to proper asbestos identification should be supported by NIOSH as well. Definitions and analytical protocols that emphasize the asbestiform crystal growth habit (the hallmark of asbestos) deserve the highest level of consideration.

R. T. Vanderbilt Company, Inc.
INDUSTRIAL MINERALS AND CHEMICALS

Screening methods such as the ASTM PCM method and the NSSGA method referenced in the draft Roadmap, the OSHA appendix sections for PLM applications in the OSHA asbestos standard, and the PLM method adopted in the UK (MDHS 77) would be a good start. Even though aspects of these methodologies are fiber size- driven, they are significantly more "asbestos"-specific than NIOSH's Methods 7400 and 7402. Such approaches need not be reinvented by NIOSH, but rather supported and improved upon, as appropriate.

5. Emphasis should be placed on the refinement of light microscopy and sampling methodology because of cost and availability. More refined analytical tools such as transmission electron microscopy should be reserved for the more complex or controversial analytical challenges. A realistic, practical approach should be maintained despite the asbestos fiber resolution issues described in the Roadmap.

6. NIOSH should adopt a policy that encourages the proper identification of all exposures regardless of risk. The more accurately exposures are identified, the more meaningful risk assessment is likely to be.

7. Risk categories such as asbestos are reasonable to use as long as they properly include similar substances with the same demonstrated risk. In the case of asbestiform winchite and richterite, for example, it would seem appropriate to include them under the generic term "asbestos" since these minerals are asbestiform amphiboles and have been shown to act biologically in the same way as other asbestiform amphiboles. For non-amphibole mineral fibers shown to pose a "same as" asbestos risk (e.g. erionite), their identity can be retained while controlling them as stringently as asbestos through the use of common regulatory phrases such as "treat as asbestos" or "apply asbestos standard".

As earlier stated, NIOSH has contributed greatly to the health and safety of workers, but we believe this has not been the case in regard to nonasbestiform amphiboles. RTV has pointed out conflicting data in this area in the past and trusts that this submission will assist NIOSH in its deliberations.

Very truly yours,

R. T. VANDERBILT COMPANY, INC.

John W. Kelse/sk

John W. Kelse,
Corporate Industrial Hygienist
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NIOSH Draft Roadmap RTV Comment Files

Files

1. Composition, particles size and prevalence of elongated amphibole cleavage fragments in RTV talc.

2. All health studies of RTV talc in chronological order with attending critiques and sample origin confirmations. Human (mortality and morbidity), animal and cell studies are included.

3. Overview of mesothelioma cases with names deleted (evaluation of available records)

4. Non-RTV talc human, animal and cell studies involving nonasbestiform amphiboles.

5. Human, animal and cell study overviews of health studies involving nonasbestiform amphiboles.

6. Documents pertaining to size dimensions of cleavage fragments and asbestos fibers with examples of improper use of current counting criteria.

7. Asbestos Standard impurity articles and documents.

8. ASTDR Expert Panel Report on Fiber Length – March 2003.

9. Documents and articles on the nature and analysis of talc fiber (all forms in RTV talc).