

A short summary of the comments received on the draft **Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research (Roadmap) V4** is presented here, along with NIOSH's responses and subsequent changes to the final *Roadmap*. The complete text of the submitted comments can be found at: <http://www.cdc.gov/niosh/docket/archive/docket099C.html>

Commenter	Summary of Comments Received	Response	Changes to Roadmap
Egilman	<p>a. Cannot convert particle counts to fiber counts</p> <p>b. Fiber counts do not address variability in fiber lengths</p> <p>In other words for each fiber greater than 5 microns there are 10,000 to 100,000,000 million fibers shorter than 5 microns and there is similar variability for the number of fibers greater than 5 microns. (See attached graphs from Nicholson for fiber distribution from various product exposures.) The same phenomenon applies to mine samples from different samples. (See Winer attached)</p>	<p>NIOSH is aware of the variability associated with converting particle counts to fiber counts, and that an air sample may have many more particles < 5 µm than are ≥ 5 µm in length. The <i>Roadmap</i> proposes that improved analytical methods based on the particle characteristics that determine their toxicity should be developed and used for exposure assessments. If the results of research indicate that lengths < 5 µm should be included in the recommended exposure limit, the recommended analytical methods used in exposure assessments should encompass these particles.</p>	No Revision.
Wylie	<p>The lack of detailed characterization of particles to which workers in epidemiological studies are exposed results in poor understanding of potency factors for size shape, mineral identity and surface properties.</p>	<p>NIOSH agrees that a more detailed characterization of the particles to which workers in epidemiological studies are exposed would provide a better understanding of the potency associated with various particle physicochemical characteristics. The <i>Roadmap</i> clearly discusses the need for comprehensive characterization of particles as part of epidemiological as well as toxicity studies.</p>	No revision

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	<p>Advocates for generation of airborne dusts from materials collected at the mine sites to recreate the distribution of particles to which cohorts in epidemiological studies were exposed.</p>	<p>Including recommendations to conduct specific research projects is outside the scope of the <i>Roadmap</i>. However, both updating previous epidemiological studies and conducting new epidemiological studies are within the scope of the research framework laid out in the <i>Roadmap</i>. NIOSH has revised the final <i>Roadmap</i> to make it even more clear that various sorts of reanalyses of previous epidemiological studies are within the proposed research framework.</p>	<p>The final <i>Roadmap</i> includes the following paragraph updated from draft <i>Roadmap</i> V4: “Outcomes from proposed research efforts outlined above in Section 3.5.2 may identify additional opportunities for informative epidemiological studies following the example of NIOSH researchers who have recently undertaken a reanalysis of data from a prior epidemiological study of asbestos textile workers after having more thoroughly characterized exposures using sample filters archived from that study [Kuempel et al. 2006]. Outcomes from the approaches outlined above in Section 3.3.2 might also potentially identify opportunities for aggregate meta-analyses of data from multiple prior epidemiological studies, allowing an assessment of risks across various types of EMPs. Recently published research illustrates the potential of such</p>

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Keise	<p>a. NIOSH presents a simplistic vision that fiber risk exists for all durable EMPs at some as yet unspecified particle dimension.</p> <p>b. The described composition of upstate NY talc in the <i>Roadmap</i> is erroneous.</p> <p>c. Mesothelioma rates in NY state counties are not necessary to discuss.</p>	<p>The current toxicological paradigm, as it was in 1990, is that dose, dimension, and durability are important determinants of particle toxicity. The decision to include nonasbestiform analogs of the asbestos minerals in the REL adopted in 1990 as a prudent public health measure was, in part, based on this paradigm because the epidemiological evidence was inconclusive.</p> <p>The talc deposits in upstate New York are complex, and the descriptions and categorizations of the minerals are the subject of ongoing debate. The <i>Roadmap</i> discusses the various interpretations of the available data.</p> <p>The issue of mesothelioma among workers in NY State counties has been a continuing issue related to the occupational exposures among miners and millers in talc mines in upstate NY. Therefore a discussion of mesothelioma in New York State counties is appropriate.</p>	<p>No Revision</p> <p>The Section 'Studies of New York Talc Miners and Millers' has been modified in the final <i>Roadmap</i> to provide additional information on sites of the mines, mineralogy of the mines, rates of mesothelioma, and critiques of the epidemiological studies conducted on these workers.</p>

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	<p>d. Explanations for why RTV talc mortality studies show inverse exposure are inappropriate and unfounded</p> <p>e. NIOSH should clearly identify RTV talc samples in animal studies</p>	<p>The <i>Roadmap</i> does not purport to definitively explain the observed inverse relationships. Rather, the <i>Roadmap</i> discusses possible explanations, and summarizes the lung cancer excess in the RTV studies as follows: "attribution of this excess to dust exposures containing talc and other minerals has been questioned because the lung cancer excess was generally found to be most pronounced in short-term workers and did not increase with cumulative exposure to talc dust. Chance or confounding from smoking or prior mining exposures is highly unlikely to fully explain the lung cancer excess observed in these studies. These findings may be at least partly explained by employment in other industries, including other mines in upstate New York." Thus, the <i>Roadmap</i> questions the attribution of the observed excess lung cancer to talc exposures.</p>	<p>No Revision</p> <p>Changes to the <i>Roadmap</i> based on these submitted comments are included in the "Responses to line-by-line NSSGA comments" found at: http://www.cdc.gov/niosh/docket/archive/docket099C.html</p>

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	<p>f. Inadequate discussion of RTV talc worker versus Vermont talc worker with respect to elongate amphibole particulate and other EMPs</p> <p>g. NMRD experience in long-term RTV talc workers should be addressed as an indicator of non-asbestos EMP risk.</p>	<p>particular discussion. The <i>Roadmap</i> is not intended to provide a detailed discussion of any one issue, but rather to highlight issues and findings of relevance for purposes of outlining a “framework” for research. In this respect, the <i>Roadmap</i> effectively points out that excess lung cancer has been observed not only in NY talc workers, but also in Vermont talc miners, even though EMPs have not been identified in the Vermont talc. A paper by Lamm and Starr (1988) is cited as noting that this provides evidence against the hypothesis that the lung cancer excess among RTV miners is related to exposure to asbestos or nonasbestiform EMPs. This seems a sufficient discussion in the context of the <i>Roadmap</i>.</p>	<p>Minor edits have been made to the <i>Roadmap</i> which reads as follows...” It has been noted [Lamm and Starr 1988] that this provides evidence against the hypothesis that the lung cancer excess among RTV miners is caused by exposure to the EMPs in RTV talc, since these were not identified in Vermont talc.”</p> <p>The following sentence has been added to the <i>Roadmap</i>: “While pleural plaques were more frequently observed, the program has identified only one worker with irregular parenchymal opacities consistent with asbestosis-like disease, results that a consulting pulmonologist ‘did</p>

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Abrams	<p>Additional submitted comments (identified as page-specific comments) are included in the document "Submission to Paul Middendorf (NIOSH) from John Hayden (National Stone Sand & Gravel Association (NSSGA)" found at: http://www.cdc.gov/niosh/docket/archive/docket099C.html</p>	<p>NIOSH responses to the submitted comments are incorporated into the document "Responses to line-by-line NSSGA comments" found at: http://www.cdc.gov/niosh/docket/archive/docket099C.html</p>	<p>The Section 'Studies of New York Talc Miners and Millers' has been modified in the final <i>Roadmap</i> to provide additional information on sites of the mines, mineralogy of the mines, rates of mesothelioma, and critiques of the epidemiological studies conducted on these workers.</p>
	<p>The characterizations of RTV talc have mostly been done by RTV.</p>	<p>The <i>Roadmap</i> discusses the complex nature of the talc deposits in upstate New York and that the descriptions and categorizations of the minerals have varied among different researchers. The nature of these minerals is the subject of ongoing debate.</p>	<p>No Revision</p>
	<p>"There is an urgent need for independent scientific cell and animal studies of the carcinogenicity of talc mined from these areas." And "There is also an urgent need for a full, independent, epidemiological study of the entire population of RTV miners and millers and their families, as well as a more global study of workers and their</p>	<p>Including recommendations to conduct specific research projects is outside the scope of the <i>Roadmap</i>. However, conducting both toxicity studies and epidemiological studies are within the scope of the research framework laid out in the <i>Roadmap</i>.</p>	<p>No Revision</p>

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Frank	<p>families exposed to products containing talc from these mines.”</p> <p>An additional eight, possibly nine, cases of mesotheliomas were identified prior to 2002, but were not included in Honda study. Also, after 2002, an additional 5 cases of mesothelioma have been documented. The dismissal by Honda of the two mesothelioma cases identified fails to account for exposure in building a talc mine by one of the workers, and that the other worked for a number years in the RTV mine when previously owned by International Talc. Also, the scientific literature does not at all address deaths from exposure to RTV industrial talc included in industrial products and marketed throughout the U.S., such as those used in industrial plasters and in foundry work.</p> <p>“There is a general sense of being apologetic of use of asbestos in amny [sic] industrial settings. It ignores many important older pieces of peer reviewed literature-eg. Wagner’s 1974 inhalation [sic] studies that are still relevant. Also how UICC reference materials were made. Specific [sic] comments- “</p> <p>“p2, lines 18-20 Implies there is a safe level</p>	<p>Unpublished information on additional mesotheliomas potentially attributable to work in the mines of upstate New York or from working with the minerals in downstream uses is now mentioned in the final <i>Roadmap</i>.</p>	<p>The following sentence has been added to the <i>Roadmap</i>: “NIOSH has recently received unpublished reports of additional cases of pleural mesothelioma among workers at RTV or its predecessor, International Talc [Abrams 2010; Maimon 2010], and of at least one worker using products from the mine who may also have died from mesothelioma [Satterley 2010].”</p>
		<p>These general comments are noted.</p> <p>The draft <i>Roadmap</i> V4 states “The</p>	<p>No Revision</p>

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	<p>of asbestos when there is none-not a viable concept.”</p> <p>“p8,line40-41 -should call for development of knowledge bases for importation figures [sic] [sic].”</p> <p>“p9,line 7-really VERY limited exceptions, not just limited-Very limited. ”</p> <p>“p11.lines 35-36-can do surveillance .”</p>	<p>Response</p> <p>generally lower current exposures give added significance to the question of whether or not there is an asbestos exposure threshold below which workers would incur no risk of adverse health outcomes.” While this states that the question of an exposure threshold has greater significance, it does not imply that a threshold exists.</p> <p>NIOSH agrees that information on importation of asbestos containing products should be tracked and publicly available.</p> <p>The use of the modifier “limited” adequately describes the restrictions on importation and uses of asbestos in the European Union.</p> <p>NIOSH maintains that it is not currently</p>	<p>Changes to Roadmap</p> <p>In Section 3.5.1 the following sentence has been added to the final Roadmap: “To complement readily available information disseminated by the USGS on annual domestic production and importation of raw asbestos, data on the annual amounts of asbestos imported into the United States in the form of any asbestos-containing products should be aggregated and made easily accessible.”</p> <p>No Revision</p> <p>No Revision</p> <p>No Revision</p>

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	<p>"p13-top-if SEER data only covers 15% of population not really relevant and should not be quoted."</p>	<p>A commenter on a previous draft of the <i>Roadmap</i> suggested the SEER data should be included in the <i>Roadmap</i>. The SEER data have been included for completeness and to demonstrate the limitations of the SEER data relative to the NORMS data.</p>	<p>No Revision</p>
	<p>"p14,lines 19-32-whole paragraph very badly done. non-malignant disease includes plaques(line25)issue of finding ab [sic]bodies too vague-all people have them, it is the number. Dx needs only proper hx of exposure and prioper [sic] change on x-ray with no other cause. These are too many criteria."</p>	<p>The criteria cited here are those recommended by the American Thoracic Society. The <i>Roadmap</i> states: "Thus, following reasonable efforts to exclude other possible diagnoses, the diagnosis of asbestosis usually rests on chest imaging abnormalities that are consistent with asbestosis in an individual judged to have sufficient exposure and latency since first exposure."</p>	<p>No Revision</p>
	<p>"p15,line 33-hx of exposure alone sufficient [sic]-see editorial [sic] Am Rev Resp Dx [sic]."</p>	<p>The criteria presented in this part of the <i>Roadmap</i> are those recommended by the American Thoracic Society.</p>	<p>The final <i>Roadmap</i> includes a sentence explaining the ATS criteria: 'As explained by the ATS [2004], "the specificity of the diagnosis of asbestosis increases with the number of consistent findings on chest</p>

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	<p>"p16, lines 1-2, need to note that chrysotile, compared to amphibols [sic] much less frequently make asbestos bodies."</p>	<p>The <i>Roadmap</i> makes it clear that "... the absence of asbestos bodies cannot be used to rule out past exposure with certainty, particularly from chrysotile exposure..."</p>	<p>Changes to <i>Roadmap</i> film, the number of clinical features present (e.g., symptoms, signs, and pulmonary function changes), and the significance and strength of the history of exposure.'</p>
	<p>"lines 13-14 - see comment above about implied safe level."</p>	<p>NIOSH believes the <i>Roadmap</i> accurately states the current understanding that "A risk-free level of exposure to airborne asbestos fibers has not been established."</p>	<p>No Revision</p>
	<p>"p17, lines 33-34- while a few do not believe chrysotile does not cause [sic] mesothelioma most do, as well as IARC, WHO etc. and this line therefore inappropriate as written."</p>	<p>The <i>Roadmap</i> reviews the evidence that chrysotile causes mesothelioma in Section 2.6.1.1 of the draft <i>Roadmap</i> V4. Because there are some who continue to argue that chrysotile does not cause mesothelioma, the statement "A related issue that continues to be debated is the potential for chrysotile fibers to cause mesothelioma and lung cancer." accurately presents the current situation.</p>	<p>The final <i>Roadmap</i> reviews the evidence that chrysotile causes mesothelioma in Section 2.7.1. The following statement has been moved to Section 2.10 "Summary of Key Issues": "A related issue that continues to be debated is the potential for chrysotile fibers to cause mesothelioma and lung cancer."</p>

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	<p>"p18, lines 27-30--amphibole hypothesis debunked--see Stayner and Frank, Dodson and Williams(1998)-UICC B is asbestos free and causes meso."</p>	<p>The <i>Roadmap</i> reviews the arguments both for and against the amphibole hypothesis, including the evidence and arguments presented in the Stayner paper.</p>	<p>A paragraph has been added to Section 2.7.1 'Chrysotile' discussing the studies in which animals were exposed to UICC chrysotile B and the analyses for amphiboles in UICC chrysotile B.</p>
	<p>"p19, lines 11-12--see Wagner 1974--chrysotile and Crocidolite [sic] equally caused meso. Hodgson and Darnton discredited by so much literature and should not even be quoted."</p>	<p>NIOSH agrees that a discussion of the animal studies conducted with UICC chrysotile B should be included in the <i>Roadmap</i>.</p> <p>The issue of differences in potency between chrysotile and the amphibole asbestos minerals has been discussed in several publications in addition to Hodgson and Darnton, and is a continuing issue that is important to include in the <i>Roadmap</i>.</p>	<p>The <i>Roadmap</i> has been modified by adding to Section 2.7.1 'Chrysotile' a discussion of additional studies that provide evidence of different potencies for lung cancer and mesothelioma between chrysotile and amphibole asbestos minerals.</p>
	<p>"p24, lines 1-22---this paragraph does not really reflect true situation and Gamble citation inappropriate [sic] given his being tossed out by NIOSH for fronting for industry."</p>	<p>NIOSH has received numerous comments on the Section 'Studies of New York Talc Miners and Millers' of the draft <i>Roadmap</i> V4. Some of the commenters provided information not available previously available to NIOSH and provided different interpretations of the available information on these workers. NIOSH has updated the final <i>Roadmap</i> to reflect this new information.</p>	<p>The Section 'Studies of New York Talc Miners and Millers' has been modified in the final <i>Roadmap</i> to provide additional information on sites of the mines, mineralogy of the mines, rates of mesothelioma, and critiques of the epidemiological studies conducted on these workers.</p>

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	<p>"Same for p25,lines 18-31--deserves NO ROLE.As for facts, even if true, the exposure is additive and contributes to disease."</p> <p>"p30,lines 17-38-even if unclear an additive risk. In general there is too much of an excuse made for RTV-NIOSH said asbestos there-then it is additive and harmful."</p> <p>"Other points-need a clear definition of "asbestosis"-which should include pleural changes as was recognized for many years, especially 1867-1938 (Zenker and then Lanza)."</p> <p>"EMP is not so much equivocal [sic] as mostly unstudied. Role of taconite, Libby etc needs more work."</p>	<p>The paragraph cited (p. 25, lines 18-31) along with the following two paragraphs review the strengths and weaknesses of the referenced Gamble study.</p> <p>The paragraph cited (p. 30, lines 17-38) reviews the strengths and weaknesses of the referenced MDH study on taconite.</p> <p>The ATS guidelines for asbestosis diagnosis are presented on p. 14 of the draft <i>Roadmap</i> V4.</p> <p>NIOSH agrees that the nonasbestiform EMPs have been largely unstudied. The <i>Roadmap</i> characterizes the available epidemiological evidence on health effects of nonasbestiform EMPs as equivocal, and indicates that additional epidemiological and toxicity studies on a variety of nonasbestiform EMPs are needed to better understand the determinants of their toxicity.</p>	<p>No revision</p> <p>No revision</p> <p>No Revision</p> <p>No Revision</p>
	<p>"Overall the draft needs to be written to be more protective of workers and others and</p>	<p>The purpose of the <i>Roadmap</i> is to present an overview of the literature, identify the</p>	<p>No Revision</p>

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	less apologetic.”	key areas of uncertainty and gaps in scientific knowledge that need to be reduced to allow NIOSH to update its recommendations for occupational exposure, and provide a framework for the research needed to reduce these uncertainties and gaps. The <i>Roadmap</i> is written in a manner that provides the strengths and limitations of the available information so that appropriate research programs can be developed to accomplish the goals set out in the <i>Roadmap</i> .	
Ellis and Allied Organizations (Allies)	<p>NIOSH should recommend research that:</p> <ol style="list-style-type: none"> a. Provides an accurate definition of asbestiform minerals b. Develops analytical methods to differentiate asbestos and “non-asbestos” c. Affirms a health risk-based level of tolerance so that harmful exposure 	<p>The <i>Roadmap</i> provides a framework for research that is intended to identify the determinants of toxicity for elongate mineral particles. Whether the term “asbestiform” might be useful in describing the determinants of toxicity is not clear at this time.</p> <p>The <i>Roadmap</i> includes a substantial discussion of the need to develop analytical methods for exposure assessment that differentiate particles based on the determinants of toxicity.</p>	<p>No Revision</p> <p>No Revision</p>
	<ol style="list-style-type: none"> c. Affirms a health risk-based level of tolerance so that harmful exposure 	The ultimate goal of the research that would be conducted within the framework	No Revision

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Van Orden	<p>to definitive asbestos and asbestiform fibers is prevented. Zero is not a feasible result for a naturally occurring substance</p> <p>NIOSH should include a comprehensive mineralogical, chemical and physical property examination of asbestos and asbestiform fibers that have been reported in the scientific literature to cause human disease.</p> <p>The comments from van Orden are included in the document "Submission to Paul Middendorf (NIOSH) from John Hayden (National Stone Sand & Gravel Association (NSSGA))" found at: http://www.cdc.gov/niosh/docket/archive/d</p>	<p>proposed in the <i>Roadmap</i> is to provide the information needed to update the recommendations for occupational exposure to elongate mineral particles. It is not knowable at this time if the results of the research will identify a risk-free exposure level. However, NIOSH policy states: "NIOSH recommended exposure limits (REL) will be based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques. To the extent feasible, NIOSH will project not only a no-effect exposure, but also exposure levels at which there may be residual risks."</p> <p>The <i>Roadmap</i> recommends an exhaustive characterization of mineral samples to which workers are exposed in epidemiological studies or are used in toxicological testing.</p> <p>The responses to the received comments are incorporated into the document "Responses to line-by-line NSSGA comments" found at: http://www.cdc.gov/niosh/docket/archive/docket099C.html</p>	<p>No Revision</p> <p>Please see the document "Responses to line-by-line NSSGA comments" found at: http://www.cdc.gov/niosh/docket/archive/docket099C.html</p>

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Berman	<p data-bbox="1323 388 1347 583">ocket099C.html</p> <p data-bbox="1177 388 1307 924">A more comprehensive and critical review of literature is needed to support development of a strategy to address future research needs.</p>	<p data-bbox="682 955 1307 1480">The purpose of the <i>Roadmap</i> is to present an overview of the literature, identify the key areas of uncertainty and gaps in scientific knowledge that need to be reduced to allow NIOSH to update its recommendation, provide a framework for the research needed to reduce the uncertainties and gaps. The <i>Roadmap</i> is intended as the first step in the process of updating NIOSH's recommendations for occupational exposure to asbestos and other elongate mineral particles. NIOSH believes the literature review provided in the <i>Roadmap</i> is sufficient to fulfill its purpose. However, to develop the specific research programs called for in the <i>Roadmap</i> NIOSH believes that additional literature reviews will be needed.</p>	<p data-bbox="998 1512 1307 1879">With the additional review of the literature based on other comments received on specific sections of the <i>Roadmap</i>, NIOSH believes the literature review provided by the <i>Roadmap</i> is sufficient to fulfill its purpose,</p>
	<p data-bbox="495 388 600 913">Human epidemiology data should be given precedence over other forms of data when evaluating asbestos risk.</p>	<p data-bbox="251 955 600 1480">NIOSH agrees that human epidemiological studies, when they are available, should be given precedence over other forms of data, such as toxicity testing, to evaluate the risk of exposure to asbestos and other elongate mineral particles. However, the opportunities to perform new or reconstructed epidemiological studies are likely to be limited, and the epidemiological studies that can be performed may not</p>	<p data-bbox="576 1512 600 1659">No Revision</p>

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	<p>Advocates for generation of airborne dusts from materials collected at the mine sites to recreate the distribution of particles to which cohorts in epidemiological studies were exposed.</p> <p>Archived filters from epidemiological studies should be reserved for research providing the greatest value.</p>	<p>provide information on exposures to all of the mineralogical variants of interest. In these cases, toxicity testing will be needed to fill in the gaps in knowledge. Additionally, the <i>Roadmap</i> calls for research to develop a suite of <i>in vitro</i> and <i>in vivo</i> toxicity tests that are highly predictive of EMP health effects in humans to enable risk management decisions that effectively protect workers before they are exposed.</p> <p>Including recommendations to conduct specific research projects is outside the scope of the <i>Roadmap</i>. However, both updating previous epidemiological studies and conducting new epidemiological studies are within the scope of the research framework laid out in the <i>Roadmap</i>.</p> <p>NIOSH agrees that the use of archived exposure samples (filters) should judiciously be used to support research programs such as updating epidemiological studies that support risk assessments, and has used them in its own studies when scientifically valid. It is also noted that the number of epidemiological studies with well-documented archived exposure samples (filters) is small.</p>	<p>No Revision</p> <p>No Revision</p>

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Ford (NSSGA)	<p>There is a need to develop and standardize nomenclature to distinguish research needs when various parameters may not be well defined.</p> <p>Soften or eliminate statements suggesting the difference or similarity of particles of biological importance in various environments.</p> <p>Additional submitted comments (identified as page-specific comments) are included in the document "Submission to Paul Middendorf (NIOSH) from John Hayden (National Stone Sand & Gravel Association (NSSGA)" found at: http://www.cdc.gov/niosh/docket/archive/docket099C.html</p>	<p>NIOSH agrees that use of standardized nomenclature in reporting research on asbestos fibers and other EMPs is important, and the <i>Roadmap</i> calls for the development and standardization of unambiguous terminology and definitions, where possible. Where necessary, this may include the development of terms which encompass a variety of particles which cannot be differentiated in practice.</p> <p>The <i>Roadmap</i> calls for exhaustive characterization of EMPs included in the research conducted within the framework proposed. This characterization in combination with the results of epidemiological and toxicity studies might enable the identification of the physicochemical particle characteristics which are of biological importance.</p> <p>The responses to the submitted comments are incorporated into the document "Responses to line-by-line NSSGA comments" found at: http://www.cdc.gov/niosh/docket/archive/docket099C.html</p>	<p>No Revision</p> <p>Changes to the <i>Roadmap</i> based on these submitted comments are included in the "Responses to line-by-line NSSGA comments" found at: http://www.cdc.gov/niosh/docket/archive/docket099C.html</p> <p>Changes to the <i>Roadmap</i> based on these submitted comments</p>

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Hayden (NSSGA)	Middendorf (NIOSH) from John Hayden (National Stone Sand & Gravel Association (NSSGA)) found at: http://www.cdc.gov/niosh/docket/archi ve/docket099c.html The comments from Hayden are included in the document "Submission to Paul Middendorf (NIOSH) from John Hayden (National Stone Sand & Gravel Association (NSSGA))" found at: http://www.cdc.gov/niosh/docket/archi ve/docket099c.html	"Responses to line-by-line NSSGA comments" found at: http://www.cdc.gov/niosh/docket/archive/ docket099c.html The responses to the submitted comments are incorporated into the document "Responses to line-by-line NSSGA comments" found at: http://www.cdc.gov/niosh/docket/archive/ docket099c.html	are included in the "Responses to line-by-line NSSGA comments" found at: http://www.cdc.gov/niosh/doc ket/archive/docket099c.html Changes to the <i>Roadmap</i> based on these submitted comments are included in the "Responses to line-by-line NSSGA comments" found at: http://www.cdc.gov/niosh/doc ket/archive/docket099c.html
Kelly (Center for Regulatory Effectiveness)	"... we recommend that NIOSH add a comment, in a footnote or otherwise, to the effect that mined talc varies from deposit to deposit, and that 'New York State talc' is recognized as distinctive for the elongate appearance of many of its particles and its composition, while pure talc is laminar in form and very different from asbestos or other elongate minerals."	NIOSH recognizes that talc deposits vary by location, and this is made clearer in the final version of the <i>Roadmap</i> .	A footnote has been added in the Section of the <i>Roadmap</i> entitled ' <i>Studies of New York Talc Miners and Millers</i> .' It states: "The characteristics of talc deposits vary with location [Van Gosen et al. 2004]. Unless otherwise specified, the talc referred to in this section is restricted to the deposits in New York State which contain talc and other minerals."
Maimon	The Honda study, published in 2002, only looked at mortality until 1989; however 4 additional deaths of former R. T. Vanderbilt workers from mesothelioma after 1990 and before 2002. Another Gouvernor [sic]Talc worker died from mesothelioma in 2005. Additional mesothelioma deaths occurred	Unpublished information on additional mesotheliomas potentially attributable to work in the mines of upstate New York is now mentioned in the final <i>Roadmap</i> .	The following sentence has been added to the <i>Roadmap</i> : "NIOSH has recently received unpublished reports of additional cases of pleural mesothelioma among workers at RTV or its predecessor,

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	<p>in workers employed in the same mines before it was purchased by R. T. Vanderbilt.</p>		<p>International Talc [Abrams 2010; Maimon 2010], and of at least one worker using products from the mine who may also have died from mesothelioma [Satterley 2010].”</p>
Satterley	<p>“There have been numerous confirmed cases of malignant mesothelioma among the employees in the Talc mines in Upstate New York. There have also been many instances of an asbestos-related lung cancer and asbestosis from the workers.” ... “In addition to R. T. Vanderbilt’s workers dying from asbestos-related diseases, there have been many instances where workers of R. T. Vanderbilt’s customers have died from asbestos-related disease. I will give just one example.”</p>	<p>Unpublished information on additional mesotheliomas potentially attributable to work in the mines of upstate New York is now mentioned in the final <i>Roadmap</i>.</p>	<p>The following sentence has been added to the <i>Roadmap</i>: “NIOSH has recently received unpublished reports of additional cases of pleural mesothelioma among workers at RTV or its predecessor, International Talc [Abrams 2010; Maimon 2010], and of at least one worker using products from the mine who may also have died from mesothelioma [Satterley 2010].”</p>
Panitz	<p>In many sections of the <i>Roadmap</i>, NIOSH appears to restrict the discussion to asbestos and its non-asbestiform analogs only, and not to other EMPs. In other sections, NIOSH often seems to exclude some or all of the other EMPs even though they have been heavily associated with known asbestos-like health effects (e.g. fibrous talc, winchite, richterite, erionite, fluoro-edenite).</p>	<p>It is necessary for NIOSH to limit its discussion to nonasbestiform analogs of the asbestos minerals when discussing the REL adopted in 1990 because the scope of the REL is limited to these minerals. NIOSH has reviewed each of the specific suggestions for changes in scope of minerals included in each of the discussions and made revisions where it is deemed appropriate. Where examples are provided</p>	<p>Numerous modifications have been made throughout the final <i>Roadmap</i>.</p>

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	<p>“the lack of uniformity in the use of terms and the lack of precision in the definitions of many of the scientific terms remain issues which cannot be resolved in this Roadmap” This unfortunate comment suggests that NIOSH is not striving for precision in its use of certain key terms, such as <u>other</u> EMPs.</p>	<p>The quoted sentence refers to the use of terms in the published literature and the lack of precision in some of the terms defined in authoritative publications. Although NIOSH strives to use precise terminology in the Roadmap, NIOSH cannot arbitrarily change the terms used by other authors without potentially misrepresenting their results or intended meaning. Nor can NIOSH impose its mineralogical definitions on the health and mineralogical scientific communities. These issues are much larger than can be resolved within the Roadmap. However, the Roadmap does call for “the development of standard terminology and definitions which are acceptable to the majority of scientists relevant to the issues of asbestos and other EMPs. NIOSH also supports the dissemination of standard terminology and definitions to the community of non-scientists and encourages adoption and usage by this community. The need for the development and standardization of unambiguous terminology and definitions warrants a priority effort of the greater scientific community that should precede,</p>	<p>No Revision</p>

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	<p>No explanation is given for designating the fibrous talc exposures of upstate New York as “nonasbestiform”, other than mentioning that the exposures have been reported to be nonasbestiform by RT Vanderbilt (Kelse 2005).</p> <p>NIOSH should emphasize that lung cancer mortality has been consistently reported to be elevated in studies of New York talc miners despite various study weaknesses that make dose-response evaluations difficult.</p> <p>NIOSH should mention that there have been a number of mesothelioma cases reported among NY talc workers.</p>	<p>or at least be concurrent with, further research efforts.”</p> <p>The talc deposits in upstate New York are complex, and the descriptions and categorizations of the minerals are the subject of ongoing debate. The <i>Roadmap</i> has been modified to discuss the various interpretations of the available data.</p> <p>In the ‘Studies of New York Talc Miners and Millers’ Section of the <i>Roadmap</i>, the issue of lung cancer mortality in epidemiological studies of the New York talc mines and mills is substantively addressed.</p> <p>In addition to this comment, NIOSH has received other comments indicating that additional mesothelioma cases have occurred among New York talc workers. The final <i>Roadmap</i> incorporates this newly received information.</p>	<p>The Section ‘Studies of New York Talc Miners and Millers’ has been modified in the final <i>Roadmap</i> to provide additional information on the mineralogy.</p> <p>No Revision</p> <p>The following sentence has been added to the <i>Roadmap</i>: “NIOSH has recently received unpublished reports of additional cases of pleural mesothelioma among workers at RTV or its predecessor, International Talc [Abrams 2010; Maimon 2010], and of at least one worker using products from the mine who may also have died from mesothelioma [Satterley 2010].”</p>

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	<p>Respiratory mortality rates in St. Lawrence County and Jefferson County in New York state are elevated.</p> <p>Vermont talc is not asbestos-free.</p> <p>The section "Some Minerals of Potential Concern Not Covered by the NIOSH REL" belongs in Section 2.6.1.3.1 'Epidemiological Studies'.</p>	<p>NIOSH agrees that more information on asbestosis and mesothelioma rates can improve the discussion of the respiratory disease pattern in upstate New York around the talc mines.</p> <p>The cited Van Gosen paper reports that "black-wall talc deposits are associated with serpentinite masses that in some areas host well-developed chrysotile asbestos" which does not clearly state that the Vermont black-wall deposits contain chrysotile asbestos." Also, Van Gosen cites others' descriptions of a deposit in a talc quarry near Chester, VT, as "radiating masses of fibrous actinolite", but does not specify these are asbestiform.</p> <p>Section 2.6.1.3.1 'Epidemiological Studies' was intended to discuss the epidemiological studies NIOSH considered when developing the 1990 recommendation for occupational exposure to airborne asbestos fibers, as well as updates to that information. The Section 'Some Minerals of Potential</p>	<p>Additional information on asbestosis and mesothelioma rates in St. Lawrence County and Jefferson County, as reported in the <i>World Surveillance Report</i>, are presented in the final <i>Roadmap</i>.</p> <p>Information from the Van Gosen paper are now included in the final <i>Roadmap</i>, as is a broadened description of the bulk and air samples presented in the Selevan et al. paper.</p> <p>The final <i>Roadmap</i> has been reorganized to present the epidemiological information more effectively, and some sections have been retitled to more accurately reflect the content of each section.</p>

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	<p>NIOSH should include information that reflects IARC's findings on talc that "there is sufficient evidence for the carcinogenicity to humans of talc containing asbestiform fibers".</p>	<p>Concern Not Covered by the NIOSH REL was intended to discuss other minerals.</p> <p>NIOSH agrees that information on IARC's findings on talc should be included in the <i>Roadmap</i>.</p>	<p>The final <i>Roadmap</i> includes the sentence: "The International Agency for Research on Cancer (IARC) has considered evidence relevant to carcinogenicity for several EMPs [IARC 1977, 1987a, 1997]. In addition to the traditional commercial asbestos IARC has made assessments that the evidence is sufficient to determine that both erionite and talc containing asbestiform fibers are human carcinogens (i.e., Group 1); the evidence for carcinogenicity of nonasbestiform talc was judged to be insufficient to determine human carcinogenicity (i.e., Group 3)."</p> <p>To more clearly reflect its content, the title of Section 3.5.3 has been changed to 'Conduct Selective Epidemiological Studies of</p>
	<p>Using the term "nonasbestiform" is inappropriate in relation to upstate New York and Vermont talc exposures. Using the term "amphiboles" is also too limiting in that the mineral talc, is not an</p>	<p>NIOSH agrees that the description "EMPs from nonasbestiform amphiboles" is too narrow in describing the minerals of interest. The <i>Roadmap</i> is now reworded to broaden the scope.</p>	

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Webber	<p>Summary of Comments Received</p> <p>amphibole.</p> <p>"Throughout the <i>Roadmap</i>, talc mined in upstate NY is referred to as nonasbestiform. This is not accurate, in that most of the "talc" produced from this area is indeed asbestiform."</p>	<p>Response</p> <p>The talc deposits in upstate New York are complex, and the descriptions and categorizations of the minerals are the subject of ongoing debate. The <i>Roadmap</i> discusses the various interpretations of the available data.</p>	<p>Changes to <i>Roadmap</i></p> <p>Workers Exposed to Asbestos Fibers and Other EMPs". Also, the cited sentence has been modified to: "Results from epidemiological studies of workers exposed to EMPs such as from nonasbestiform amphibole minerals or minerals in talc deposits have provided limited, if any, evidence in support of an association between occupational exposure and lung cancer or mesothelioma."</p> <p>The Section 'Studies of New York Talc Miners and Millers' has been modified in the final <i>Roadmap</i> to provide additional information on the mineralogy.</p>
	<p>The <i>Roadmap</i> discussion of mass percentages on page 26, lines 18-36, is misleading because a health-related investigation of the ore would ignore the high-mass large particles because they never become airborne, let alone respirable.</p>	<p>The discussion on page 26 lines 18-36 of the draft <i>Roadmap</i> V4 provides an overview of the of the mineralogical content of RTV mines, and its inclusion is consistent with the National Academies recommendation for a tiered approach to characterization¹ of minerals to which</p>	<p>No Revision</p>

¹Institute of Medicine and National Research Council [2009]. A Review of the NIOSH *Roadmap* for Research on Asbestos Fibers and Other Elongate Mineral Particles. Washington, DC: The National Academies Press. See pp 39-48.

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	<p>The <i>Roadmap</i> wrongly downplays TEM's capability in two sections. On page 34, lines 33 and 34, the <i>Roadmap</i> states that TEM "frequently cannot differentiate nonasbestiform from asbestiform EMPs". This is misleading in that EMPs in air samples will seldom exhibit asbestiform morphology.</p> <p>The <i>Roadmap</i> neglects to mention that PCM is likewise incapable of differentiating nonasbestiform from asbestiform morphologies.</p> <p>Further down in lines 36-37, the <i>Roadmap</i> continues: "Important limitations of TEM are that partial lengths of long fibers that intersect grid bars can be hidden due to the small field of view..." This is another non-issue in that very few airborne asbestos fibers are long enough to make this a reality.</p>	<p>workers in epidemiological studies are exposed and in toxicity testing.</p> <p>The <i>Roadmap</i> accurately describes a limitation of TEM under certain conditions specified in the <i>Roadmap</i> — when the elemental composition is the same or when present in a heterogeneous mix of unknown particles, TEM frequently cannot differentiate nonasbestiform from asbestiform.</p> <p>In draft <i>Roadmap</i> V4, on p. 34, lines 32-33, it is stated that "PCM ... is not equipped for particle identification."</p> <p>NIOSH agrees that, on air samples, few long fibers will be present that intersect grid bars, and accordingly modifies the description of this potential limitation of TEM for analysis of exposure samples.</p>	<p>No Revision</p> <p>No Revision</p> <p>The final <i>Roadmap</i> has been modified and now states: "A potential limitation of TEM is that partial lengths of long fibers that intersect grid bars can be hidden due to the small field of view; however, this is likely to affect only a small number of observed particles as very few particles are greater than 15 µm length as evidenced in air samples from textile processing [Dement et al. 2009] and mining and</p>

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	<p>It would be remiss of NIOSH to continue PCM as the standard for measuring airborne EMP's. ... Future risk assessment models will almost certainly rely heavily on TEM generated data, so NIOSH would be remiss to depend on PCM measurements into the future.</p>	<p>NIOSH views PCM as the preferred current method because the current regulations and recommendations for occupational exposure are based on risk assessments using PCM fiber counts, or conversions from particle counts to PCM fiber counts. However, on p. 92 of the draft <i>Roadmap</i> V4, NIOSH acknowledged that different analytical methods are likely to be needed – “Changes in how EMPs are defined for regulatory purposes will likely have to be accompanied by improvements to currently used analytical methods or development and application of new analytical methods.”</p>	<p>milling operations [Gibbs and Hwang 1980].” No Revision</p>