UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX

# Response to the November 2005 National Stone, Sand & Gravel Association Report Prepared by the R.J. Lee Group, Inc "Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project"

**April 20, 2006**

**United States Environmental Protection Agency Region 9**
**Response to the November 2005 National Stone, Sand & Gravel Association report prepared by the R.J. Lee Group, Inc:**
**"Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project"**

This document constitutes the United States Environmental Protection Agency Region 9 (EPA Region 9) response to the major findings and conclusions of the National Stone, Sand & Gravel Association report "Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project" prepared by the R. J. Lee Group (R. J. Lee Report). A more detailed analysis will be completed after additional information is received from the R. J. Lee Group and the National Stone, Sand & Gravel Association,[1] and the United States Geological Survey (USGS).

The R. J. Lee Report draws conclusions that are contradicted by the El Dorado Hills data and by generally accepted scientific principles for measuring asbestos exposure.

## Overview

The R. J. Lee Group review of the EPA data was contracted by the National Stone, Sand & Gravel Association. The El Dorado County Office of Education funded the three reviewers who wrote letters in support of the R. J. Lee Report and whose reviews are included in this response.

The EPA Region 9 El Dorado Hills Naturally Occurring Asbestos Exposure Assessment was designed to measure the exposures to asbestos fibers, if any, that resulted from sports and play activities that disturbed dust and soil. EPA Region 9 adhered to accepted EPA standards for sampling and analysis, including rigorous quality assurance/quality control, and to the standard methodologies of EPA exposure and risk assessment.

**The R. J. Lee Report Criticizes EPA Region 9 for Using Established Scientific and Public Health Protocols -** In assessing naturally occurring asbestos exposures in El Dorado Hills, EPA evaluated asbestos exposures using the PCME (phase contrast microscopy equivalent) asbestos fiber size classification. The PCME classification was used because human epidemiological studies, which form the basis of knowledge of asbestos health effects, measured asbestos fiber concentrations using phase contrast microscopy (PCM) analytical methods. PCME is the standard term for fibers counted by more modern analytical methods that are of equivalent size to those fibers that would be seen by PCM analysis, and includes fibers with a length to width aspect ratio of 3 to 1 or greater. EPA considered PCME fibers in our analysis of the El Dorado data to be consistent with the existing health databases and risk assessment

[1]On March 9, 2006, EPA Region 9 sent a letter to the R.J. Lee Group and the National Stone, Sand, & Gravel Association asking for additional information to support the findings and conclusions of the R.J. Lee Report.

procedures used by EPA, California EPA (Cal/EPA), the World Health Organization, and other federal agencies and international organizations. This approach was rejected by the R.J. Lee Group, which instead advocates use of asbestos fiber definitions which are not health based or supported by the majority of experts in the health community, and which would not allow comparison to the existing epidemiologic data on asbestos related cancers.

**The R. J. Lee Report Claims that EPA Region 9 Misapplied Fiber Counting Protocols** - The R. J. Lee Report claims that EPA Region 9 inflated the fiber counts in the El Dorado Hills air data by misapplying the International Standards Organization (ISO) method 10312 (the analytical method used by EPA to analyze the El Dorado air samples) and including PCME structures with a 3 to 1 length to width aspect ratio in our analysis. The R. J. Lee Report maintains that EPA should only have counted structures which met the general 5 to 1 aspect ratio fiber size definition described in the body of the ISO 10312 method. However, Annex C and Annex E of the ISO 10312 method specifically authorize the counting of PCME structures with a 3 to 1 aspect ratio. Another example of misleading information is the R.J. Lee Report's statistical evaluation and resulting conclusions regarding the concentrations of asbestos structures detected in the EPA air samples. All of the established EPA, National Institute of Occupational Safety and Health (NIOSH), and ISO analytical methods require the counting of asbestos bundles, recognizing the significance of bundles to proper characterization of asbestos fiber levels. The R.J. Lee Report did not include asbestos bundles in its analysis of the data, thereby undercounting the number of structures.

**The R. J. Lee Report Claims that EPA Region 9 Misidentified Amphibole Minerals** - The R. J. Lee Report concludes that EPA misidentified actinolite asbestos fibers in the El Dorado soil samples by using inappropriate extinction angle criteria. The R. J. Lee Group conclusion is contradicted by the National Institute of Standards and Technology (NIST) and the major analytical methods used for analysis of asbestos in soil and bulk samples. The R. J. Lee Report also cites an unpublished 1980 draft report to support its contention that structures found in the EPA air samples are not asbestos, and ignores a subsequent 1981 published report by the same author that actually supports the EPA approach.

**The R. J. Lee Report Applies a Geologic Definition rather than a Public Health Definition to Characterize Microscopic Structures** - The R. J. Lee Report relies heavily on the geologic distinction between asbestos fibers and cleavage fragments of the same dimensions, with the implication that exposure to cleavage fragments is benign and of little or no health significance. For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape. The EPA Region 9 approach, which is supported by most public health agencies and scientists, as well as the American Thoracic Society, is based on the following: (1) The epidemiologic and health studies underlying EPA and Cal/EPA cancer risk assessment methods were based on exposures to both cleavage fragments and fibers, and were unable to distinguish between the two, (2) The most recent panel of experts to review asbestos risk assessment methods, the 2003 Peer Consultation Panel convened by EPA, concluded that "it is prudent at

this time to conclude equivalent potency [of cleavage fragments and fibers] for cancer,"[2] (3) No well-designed animal or epidemiological studies have adequately tested the hypothesis that cleavage fragments with the same dimensions as a fiber are benign or that the human body makes any distinction, (4) Studies that purport to show that cleavage fragments are benign are questioned by many asbestos health experts, (5) There are no routine asbestos air analytical methods, including those used by EPA, NIOSH, the Mine Safety and Health Administration (MSHA), the American Society for Testing and Materials (ASTM), and ISO which differentiate between cleavage fragments and crystalline fibers on an individual fiber basis.

**The R. J. Lee Report's "Virtual" Review of EPA Region 9's Air Samples is Inconsistent with Established Laboratory Practices** - The R.J. Lee Group did not have access to EPA's actual air samples, nor did it collect any air samples of its own. Rather it reviewed limited pictures and spectra data of a small number of EPA's air samples and drew conclusions based on those representations. Such a virtual review is not consistent with the National Voluntary Laboratory Assurance Program (NVLAP) quality assurance procedures nor the verification methods of the National Institutes of Standards and Technology.

**Federal Courts Have Supported EPA** - Many of the assertions of the R. J. Lee Report are consistent with positions that the R.J. Lee Group took as an expert witness for W.R. Grace in the Libby, Montana litigation. In this litigation, the written opinions of the District and Appeals courts, while not specifically addressing the opinions of the R.J. Lee Group, rule in favor of EPA and expressly hold that EPA's experts and science are credible.[3]

## Background

In October 2004, the EPA Region 9 Superfund site assessment program conducted an assessment of exposures to naturally occurring asbestos (NOA) in El Dorado Hills, California. Specifically, EPA Region 9 simulated the sports activities of children and adults at three schools and a community park and, using personal air monitors, measured asbestos levels in the breathing zones of participants. EPA Region 9 also collected samples of ambient air in the area of the sampling at the same time the simulations were conducted to serve as reference samples. The personal activity-based samples were then compared to the reference samples. The Asbestos Hazard Emergency Response Act (AHERA)[4] regulation Z-test for statistical

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[2]USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page viii.

[3] See U.S. v. W.R. Grace, 280 F Supp 2d 1149 (2003): U.S. v. W.R. Grace, 429 F. 3d 1224, 1245 (9th Cir. 2005) (Although debate regarding testing methodology and data analysis is "exceedingly complex", EPA did not ignore accepted scientific principles)

[4]The Asbestos Hazard Emergency Response Act (AHERA) was passed by Congress in 1986 to provide for the inspection and mitigation of asbestos in school buildings. Regulations implementing the Act were promulgated by EPA in 1987.

significance was applied to determine whether there were any statistically significant differences between the personal exposure samples and the ambient reference samples. EPA Region 9 collected over 400 air samples and generated over 7000 data points. All of EPA Region 9's's analyses were conducted by accredited laboratories using recognized methods and procedures with strict quality assurance control, including blind performance samples to check analytical accuracy.

Amphibole asbestos, which many health scientists consider to be even more toxic than chrysotile asbestos, was found in almost all the reference and activity-based samples. Of the 29 different sets of activity-based scenario measurements, application of the Z-test determined that personal exposures from 24 scenarios were significantly elevated over the reference samples. Most importantly, the data showed that children and adults participating in sports activities in areas where asbestos occurs naturally in the surface soils, as it does in El Dorado Hills, can be exposed to asbestos fibers of health concern at up to 62 times the corresponding reference levels.

EPA Region 9 released the data from the assessment in May 2005 and held a public meeting in El Dorado Hills that was attended by more than 1000 members of the public. From the outset of the assessment, EPA Region 9 made clear to the community that EPA's only intent was to gather data on potential exposures. The community and the State and local regulatory agencies could then use the information to make decisions about the significance of those exposures and determine appropriate control measures. Both EPA Region 9 and the Agency for Toxic Substances and Disease Registry (ATSDR) have informed the community that exposure levels are a main determinant of the risk of developing asbestos-related cancers and non-cancer diseases, and that reducing the exposures reduces the risk. Consistent with its intent, EPA Region 9 has actively engaged the State and local regulatory agencies to improve naturally occurring asbestos mapping, monitoring, dust control, and regulation. El Dorado County has recently adopted more stringent dust control ordinances.

**Detailed Comments on the R. J. Lee Report**

**R.J. Lee Finding #1: "Based on Mineralogy, Sixty-Three Percent (63%) of the Amphibole Particles Identified as Asbestos Fibers can not be Asbestos."**

The R. J. Lee Report argues that there is too much aluminum in 63% of EPA Region 9's identified fibers for the fibers to be asbestiform.[5] In addition, the remaining 37% (sometimes the Report uses 35%) are not asbestos fibers based on their particle dimensions.

**EPA Response**

**Aluminum -** Analysis of the EPA Region 9 El Dorado air samples was performed using the International Standards Organization (ISO) method 10312, a state-of-the-art

[5]Asbestiform: Having the form or structure of asbestos.

Transmission Electron Microscope (TEM)[6] method with energy dispersive spectroscopy (EDS)[7] that has strict counting rules and characterizes the dimensions and chemistry of every fiber identified by the microscopist. Identification of fiber type was performed according to the general guidelines of the International Mineralogical Association (IMA) (Leake, 1997)[8], the international standard for amphibole nomenclature. This same approach for asbestos classification is recommended in the "Research Method for Sampling and Analysis of Fibrous Amphibole in Vermiculite Attic Insulation", EPA 600/R-04/004, January 2004, and was one of the tools used by Meeker et al (2003)[9] to determine the composition and morphology of amphiboles from Libby, Montana.

The R. J. Lee Report claims that 63% of the amphibole fibers identified by the EPA laboratory[10] as actinolite asbestos have concentrations of total aluminum that are too high to form asbestos fibers. According to page 2 of the R. J. Lee Report, "Particles with more than 0.3 aluminum atoms pfu [per formula unit] or about 1.5 percent $Al_2O_3$ cannot form in the asbestos habit due to crystal lattice constraints." To support its argument, the R. J. Lee Report cites three references. However, on close examination, two of the three references do not agree with the upper threshold limit that the R.J. Lee Group puts on total aluminum content (Leake et al, 1997) (Deer, Howie and Zussman, 1997)[11]. The third reference (Verkouteren & Wylie, 2000)[12] draws its conclusions on examination of a

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[6]Transmission Electron Microscopy (TEM) produces images of a sample by illuminating the sample with an electron beam in a vacuum, and detecting the electrons that are transmitted through the sample.

[7]Energy Dispersive Spectroscopy (EDS) uses measurement of the energy and intensity of X-rays generated when a selected area of a sample is irradiated with an electron beam to identify the mineralogical composition of a structure.

[8]B.E. Leake et al (1997). Nomenclature of Amphibole: Report of the Subcommittee on Amphiboles of the International Mineralogical Association, Commission on New Minerals and Mineral Names. American Mineralogist, Volume 82, pages 1019-1037.

[9]G.P. Meeker et al (2003). The Composition and Morphology of Amphiboles from the Rainy Creek Complex, Near Libby, Montana. American Mineralogist, Volume 88, pages 1955-1969.

[10]In this document, the terms "EPA laboratory" and "EPA Region 9 laboratory" refer to the private laboratories that conducted the analysis of the EPA soil and air samples under contract to EPA Region 9.

[11]W.A. Deer, R.A. Howie, and J. Zussman (1997). Rock-Forming Minerals: Double Chain Silicates, Vol 2, second edition, p 137 - 145.

[12]J.R. Verkouteren and A.G. Wylie (2000). The Tremolite-Actinolite-Ferro-Actinolite Aeries: Systematic Relationships Among Cell Parameters, Composition, Optical Properties, and

small set of fibrous actinolite asbestos samples which the authors partition into asbestos and fibrous "non-asbestos" byssolite using criteria which the IMA specifically recommends against, and which is inconsistent with all standard asbestos analytical methods. Perhaps most important is the fact that all three references agree that it is the IMA criteria which primarily govern the general classification of amphibole type, not the total aluminum content. These references therefore actually support the classification approach taken by the EPA laboratory.

The R.J. Lee Group did not have access to the EPA air samples to conduct their own analyses. Instead, the R.J. Lee Group looked at a limited number of photographs of the recorded EDS spectra. Interferences by other elements in the sample can affect the aluminum total in the spectra. This is especially important because the EPA samples were of air releases from soil, not processed asbestos material. Soils contain non-asbestos mineral and biological particles that can influence element totals in an EDS spectrum, most notably clay particles, which are high in aluminum. The laboratory used by EPA Region 9 identified aluminum-rich actinolite asbestos, by applying the IMA classification guidelines to its direct analysis of the actual sample.[13]

**Particle Dimension -** As previously stated, the R. J. Lee Report claims that 37% of the fibers counted by EPA in the El Dorado Hills air samples are not asbestos fibers based on their particle dimensions. The report claims that EPA Region 9 inflated the fiber counts by including asbestos structures which do not meet the definition of a fiber as described in ISO 10312. The general ISO 10312 method requires the counting of every asbestos structure with a length to width aspect ratio of 5:1 or greater. As directed by Region 9, the EPA laboratory counted structures with a 3:1 or greater aspect ratio. The R. J. Lee Report states that EPA erred in counting structures with aspect ratios less than 5:1. **Annex C and Annex E of the ISO method clearly authorize the counting of PCME structures with a 3:1 aspect ratio if the data are to be used for exposure or risk assessment purposes, the stated goal of the El Dorado Hills assessment. In fact, the ISO method contains numerous references to PCME fibers. PCME fibers are defined as fibers greater than 5 microns in length, and 0.25 to 3 microns in width with a 3:1 aspect ratio.[14] PCME fibers form the basis for EPA's IRIS toxicity database and the asbestos risk models of California EPA and other federal and international organizations.[15]**

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Habit, and Evidence of Discontinuities. American Mineralogist, 85, p. 1239 - 1254.

[13]Personal communication with John Harris, Lab/Cor, January 2006.

[14]World Health Organization (1986). Environmental Health Criteria 53, International Programme on Chemical Safety, Asbestos and Other Natural Mineral Fibres, section 2.3.2.2.

[15]The IRIS asbestos cancer inhalation unit risk, a measure of asbestos cancer potency, is based on the EPA 1986 Airborne Asbestos Health Assessment Update (EPA/600/8-84/003F; 1986). Cal/EPA used a similar approach and data sets to derive its cancer unit risk. Both the IRIS and the Cal/EPA cancer potency values rely on human epidemiological studies that were conducted using phase contrast microscopy (PCM) analytical methods (some were midget

The R.J. Lee Group also manipulates its statistical analysis of the El Dorado Hills air data by ignoring counts of asbestos fiber bundles in its evaluations. Bundles are two or more attached parallel asbestos fibers which can have a significant health impact when they are inhaled and separate into individual fibers. Bundles were counted in the historical epidemiological studies which form the basis of our knowledge of asbestos-related health effects and EPA's IRIS database. **All of the established EPA, NIOSH, and ISO analytical methods require the counting of asbestos bundles, recognizing the significance of bundles to proper characterization of asbestos fiber levels.**

The R. J. Lee Report further states that EPA's data inflated the asbestos fiber count by ignoring the Agency's own "definition" of asbestos. To support this claim, the R.J. Lee Report cites the glossary of "Method for Determination of Asbestos in Bulk Building Materials", EPA 600/R-93/116, 1993, which states, in part, "With the light microscope, the asbestiform habit is generally recognized by the following characteristics: Mean aspect ratios ranging from 20:1 to 100:1 or higher for fibers longer than 5 microns." The building material analytical method is designed to detect commercially processed asbestos in items like floor tiles, roofing felts, paper insulation, paints, and mastics, not naturally occurring asbestos on air filters or in soil samples. To present the 20:1 aspect ratio for commercial grade asbestos as a universal EPA policy, and to advocate its use as an appropriate standard for analyzing air samples of naturally occurring asbestos is inappropriate and contradictory to use of the PCME dimensional criteria as a tool for assessing exposure risk.

The R. J. Lee Report also states that the diffraction pattern analyses produced by the EPA laboratory for the El Dorado Hills air samples demonstrates that the particles identified by the laboratory are not asbestos.[16] The report cites a 1980 unpublished draft study by S.J. Ring to support its conclusion. The R. J. Lee Report does not mention a 1981 published article by the same author which revises the findings such that they no longer support the conclusion of the R. J. Lee Report and, in fact, support the data produced by

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impinger data converted to PCM counts) that could not distinguish fibers that were 5 microns in length or less. PCM cannot distinguish between fibers and cleavage fragments. PCM is not as powerful as current Transmission Electron Microscope (TEM) methods (400X vs 20,000X) as TEM can see the thinner/shorter fibers. However, since EPA's (and Cal/EPA 's) toxicity database relies on human health studies that used PCM, current EPA risk procedures use the more powerful TEM method but report the PCM equivalent (PCME) fibers and only use the PCME counted fibers in a risk assessment. This is because the IRIS asbestos file specifies that only PCME fiber counts be used with inhalation unit risk for risk calculation. See also the reference cited in footnote 11.

[16]Diffraction pattern analyses irradiates a sample with x-rays and then takes an x-ray photograph.

EPA.[17]

**R.J. Lee Finding #2: "The Laboratory Procedures did not Comply With the NVLAP Quality Assurance Standard."**

The R. J. Lee Report says that the false positive rate in our air samples was 35% when the acceptable limit in the National Voluntary Laboratory Accreditation Program (NVLAP) is 10%.

**EPA Response**

The laboratories used by EPA Region 9 for analysis of the El Dorado Hills air and soil samples are accredited through the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP is administered by the National Institute of Standards and Technology, a non-regulatory agency within the U.S. Commerce Department. A large part of the accreditation process involves on-site audits performed by NVLAP-certified inspectors who review laboratory operational and quality assurance compliance parameters, including documentation proving compliance with NVLAP requirements for verification analyses. A laboratory must demonstrate that all analysts reporting data meet the false negative and false positive requirements set forth by NVLAP before an accreditation certificate is issued. To make a determination that a laboratory did not comply with NVLAP verification standards would require a very detailed examination of all laboratory generated raw data, project specific information, such as a site-specific EPA issued Quality Assurance Project Plan, laboratory instrument log books, and other data and information not supplied in an analytical report. Interviews with the laboratory manager, quality assurance manager, and involved analysts are also mandatory to make judgement on a laboratory's possible non-compliance. The R.J. Lee Report's conclusion that the EPA laboratory was not in compliance with NVLAP, based on a cursory review of count sheet and other limited data without the in-depth examination detailed above, is therefore invalid and cannot be used to question EPA's analytical results.

EPA chose NVLAP-accredited laboratories for the El Dorado Hills assessment as a minimum quality requirement. For supplemental quality assurance, the laboratories were subjected to on-site audits performed by EPA's Quality Assurance Technical Support group, and both laboratories were sent performance evaluation samples prior to analysis of the El Dorado samples. In addition, the laboratory conducting the air sample analysis was sent double blind performance evaluation samples during the sampling event. In all cases, the laboratories successfully identified the amounts and types of asbestos present on the blind samples within acceptable limits. Further, the El Dorado Hills air and soil data were validated by a third party in accordance with standard EPA quality assurance

[17]S.J. Ring (1981). Identification of Amphibole Fibers, Including Asbestos, Using Common Electron Diffraction Patterns. In Russell P.A. and Hutchings A.E. (Eds), Electron Microscopy and X-ray Applications to Environmental and Occupational Health Analysis, Vol. 2:175-198, Ann Arbor Science Publ., Inc.

procedures and were found to be acceptable for all uses.

**R. J. Lee Finding #3: "The Soil Samples do not Demonstrate the Presence of Amphibole Asbestiform Minerals."**

The R. J. Lee Report states that the actinolite asbestos fibers identified in the El Dorado Hills soil samples contain too much aluminum to be asbestiform and that the extinction angles of the fibers indicate that they are non-fibrous cleavage fragments. The R.J. Lee Group's analysis of 23 split soil samples from EPA's October 2004 sampling event found no asbestos in the samples.

**EPA Response**

**Aluminum** - The R. J. Lee Report states that the aluminum content of the fibers in the soil samples was too high to be asbestiform actinolite and that it was indicative of non-asbestiform actinolite and another amphibole, hornblende, which contains approximately 10-20% by weight $Al_2O_3$ (5.3-10.6% by weight aluminum). Both the laboratory performing EPA's El Dorado soil sample analysis and the laboratory which analyzed the EPA air samples noted significant quantities of hornblende in the samples, but did not count or report those particles as asbestos. Please see the EPA response to Finding #1 for a further discussion of the aluminum issue.

**Extinction Angles** - The extinction angle of a fiber evaluated by polarized light microscopy is one of many criteria used to identify mineralogical composition. The extinction angle for amphibole asbestos fibers is the difference in degrees between the long axis of the fiber and the angle at which the fiber optically disappears (the polarization direction where the light passing through it becomes "extinct") when the fiber is rotated under a polarized light microscope. The R.J. Lee Report states that amphibole asbestos fibers have a zero-degree extinction angle and that non-asbestos cleavage fragments have non-zero extinction angles. Therefore, because the EPA soil sample analysis reported extinction angles which, according to the R.J. Lee Group, averaged $12^o$, the report alleges EPA incorrectly identified cleavage fragments as asbestos fibers.

**The R.J. Lee Report's conclusion regarding extinction angles is contradicted by the National Institute of Standards and Technology (NIST) and the major analytical methods used for analysis of asbestos in soil and bulk samples.** NIST certifies and provides Standard Reference Materials (SRM) for laboratory instrument calibration and laboratory accuracy measurement. The NIST Tremolite/Actinolite SRM 1867A is a special set of three samples certified by NIST to be of ultra-high purity tremolite, actinolite, and anthophyllite asbestos and is considered the "gold standard" for asbestos analytical laboratories. The material is rigorously characterized and is accompanied by a six-page document that describes the properties of each sample. It is required that all analytical laboratories accredited by NIST/NVLAP have the material in their possession and that they use it to calibrate their operations and to test their analysts. The NIST SRM

1867A certificate which accompanies the samples of tremolite and actinolite states that the reference tremolite can have an extinction angle of up to 16.6 $\pm$ 0.3° and that the actinolite can have an extinction angle of up to 15.9$\pm$0.2°. When the EPA laboratory processed the NIST actinolite standard in the manner of the El Dorado Hills soil samples, the extinction angles of the fibers in the processed standard sample were consistent with allowed maximum extinction angles for tremolite/actinolite asbestos (~ 10° to 20°) and the extinction angles of the fibers seen in the EPA soil samples.[18]

Further, the laboratory methods of EPA, NIOSH, and other agencies for analysis of asbestos in bulk material all state that tremolite-actinolite asbestos fibers may have zero (parallel) or *non-zero* (inclined or oblique) extinction angles. EPA Method 600/R-93/116[19], the standard method used by all NIST/NVLAP accredited laboratories to test building materials for the presence of asbestos, states in Table 2-2, Optical Properties of Asbestos Fibers, that tremolite-actinolite asbestos has extinction "parallel and oblique (up to 21°)." NIOSH Method 9002[20], the method used for analysis of the El Dorado Hills soil samples, states directly that actinolite and tremolite fibers exhibiting inclined extinction are to be considered asbestos. The method further states that "If anisotropic fibers are found (during PLM analysis), rotate the stage to determine the angle of extinction. Except for tremolite-actinolite asbestos which has oblique extinction at 10-20°, the other forms of asbestos exhibit parallel extinction... Tremolite may show both parallel and oblique extinction."[21]

**R.J. Lee Finding #4: "The ISO 10312 Analytical Method can not Distinguish Between Asbestos Fibers and Non-Asbestos Cleavage Fragments."**

The R.J. Lee Report states that the ISO 10312 method contains the disclaimer that "The method cannot discriminate between individual fibers of asbestos and non-asbestos analogues of the same amphibole material," and, therefore, EPA inflated the asbestos air concentrations by counting "cleavage fragments."

**EPA Response**

The ISO 10312 method cannot differentiate between fibers and cleavage fragments with

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[18]M. Bailey (2006). Identification of Asbestiform Tremolite/Actinolite. Naturally Occurring Asbestos Workgroup Meeting Presentation.

[19]USEPA (U.S. Environmental Protection Agency) (1993). Method for the Determination of Asbestos if Bulk Building Materials. EPA Method 600/R-93/116.

[20]NIOSH (National Institute for Occupational Safety and Health) (1992). Asbestos (Bulk) by PLM.. Method 9002 (Issue 2).

[21]NIOSH (National Institute for Occupational Safety and Health) (1992). Asbestos (Bulk) by PLM.. Method 9002 (Issue 2). Qualitative Assessment, Item c, page 4.

the same dimensions and chemical composition. No routine analytical method has a protocol for distinguishing fibers from cleavage fragments on an individual particle basis. Additionally, from a health standpoint, there is no evidence that supports making the distinction.

Cleavage fragment is a geologic term which refers to structures that form when non-fibrous forms of asbestos minerals split along crystallographic planes, as opposed to asbestos fibers which form from crystalline growth. The R.J. Lee Report maintains that there is a toxicological difference between asbestos structures which formed as fiber crystals and fibers which formed by cleavage plane separation. Page 3 of the R.J. Lee Report states that cleavage fragments are "not known to produce asbestos-like disease." **It is the position of EPA, the U.S. Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry (ATSDR) and National Institute for Occupational Safety and Health (NIOSH), and the American Thoracic Society, among others, that microscopic structures of amphibole and serpentine minerals that are asbestiform and meet the size definition of PCM fibers, should be counted as asbestos, regardless of the manner by which they were formed.** There are four reasons why the health agencies have taken this position: (1) The epidemiologic and health studies underlying EPA, and California EPA, cancer risk assessment methods were based on exposures to both cleavage fragments and fibers, but were unable to distinguish between the two, (2) The most recent panel of experts to review asbestos risk assessment methods, the 2003 Peer Consultation Panel convened by EPA, concluded that "it is prudent at this time to conclude equivalent potency [of cleavage fragments and fibers] for cancer,"[22] (3) No well-designed animal or human epidemiological studies have been conducted to date to test the hypothesis that cleavage fragments with the same dimensions of a fiber are benign, or that the human body makes any distinction, and studies that purport to show that cleavage fragments are benign are questioned by many asbestos health experts,[23] (4) There are no routine air analytical methods, including those used by EPA, NIOSH, the Mine Safety and Health Administration (MSHA), the American Society for Testing and Materials (ASTM), and the ISO which differentiate between cleavage fragments and crystalline fibers.

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[22]USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page viii.

[23]Both Addison (Addison J, Davies LST. 1990. Analysis of amphibole asbestos in chrysotile and other minerals. Ann Occ Hyg, Apr;34(2):159-75) and members of the U.S. EPA 2003 Peer Consultation panel raised concerns about interpretation of the Davis study (Davis JM, McIntosh C, Miller BG, Niven K. 1991. Variations in the carcinogenicity of tremolite dust samples of differing morphology. Ann NY Acad Sci, Dec;643:473-90 ), which attempted to compare the toxicity of asbestos fibers and cleavage fragments. These concerns reflected the lack of peer review, use of intra peritoneal injection instead of inhalation exposure, significance of mesotheliomas caused by structures reported as cleavage fragments, purity of the cleavage fragment samples and issues related to fiber dimensions.

In terms of epidemiological data and health outcomes, the cleavage fragment argument is without merit. For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape.

**There are no recognized analytical protocols, including those used by EPA, NIOSH, MSHA, ASTM, and ISO, which include criteria to differentiate between cleavage fragments and crystalline fibers.** All these methods require that structures which meet their definition of the specific counting rules for an asbestos fiber be counted. The requirements are based on the fact that, in the words of an expert from the United States Geological Survey, "At a microscopic level, distinguishing between these forms on single [asbestos] particles, can be extremely difficult to impossible."[24] As noted above, R.J. Lee made a very similar claim with regard to cleavage fragments as the expert witness for W.R. Grace in the Libby, Montana, Superfund cost recovery litigation. The EPA analytical experts who reviewed the R.J. Lee Group's testing methodology related to the Libby site found that the R.J. Lee laboratory could not demonstrate any reliable criteria with which to distinguish, at the microscopic level, asbestos cleavage fragments from asbestos fibers of the same size, shape, and composition. The Ninth Circuit Court of Appeals recognized the competing scientific arguments but found that EPA's position was consistent with the record of evidence and accepted scientific principles.[25]

**R.J. Lee Finding #5: "Applying the Latest Science and Definitional Techniques, the El Dorado Hills Study Shows no Significant Exposure to the Type of Amphibole Asbestos Fiber Connected To Health Risk."**

The R. J. Lee Report claims that the latest science for measuring the risk posed by asbestos is the Berman-Crump Asbestos Risk Assessment Protocol ("Berman-Crump") which proposes that amphibole asbestos fibers which are more than 10 microns long and less than 0.5 microns wide (protocol fibers) are the most toxic. Of the 2,386 fibers which the R. J. Lee Report states the EPA laboratory identified, the R.J. Lee Report concludes that only 7 fibers meet the "Berman-Crump" definition. Therefore, the R.J. Lee Group maintains that EPA has overstated the risk from exposure to asbestos fibers in El Dorado Hills.

**EPA Response**

The "Berman-Crump" protocol that the R.J. Lee Report references is in fact a draft EPA method. EPA had the method reviewed by a peer consultation panel in 2003. The panel made a number of important recommendations that must be addressed before the method can be used for EPA risk assessments. A number of important revisions have been made

[24]G.P. Meeker, USGS, (2002). Review of Expert Report of R.J. Lee.

[25]U.S. v. W.R. Grace, 429 F.3d at 1245.

to the draft method since 2003, but at this time the method has not been independently peer reviewed. It will not be adopted by EPA as a risk assessment tool unless and until it passes rigorous internal and external peer review.

The expert peer panel has recommended that the fiber size for the draft EPA risk assessment method be adjusted to include fibers greater than 5 microns in length and up to 1.5 microns in width.[26] The change is designed to account for lung deposition of fibers that results when fibers are inhaled through the mouth, and not filtered by the nasal passages. The broadening of the fiber definition to include inhalation by "mouth breathers" is especially relevant to the El Dorado Hills data. Our investigation measured personal asbestos exposures of individuals participating in sports activities, where physical exertion would likely increase breathing through the mouth. **The PCME fibers counted in the EPA air samples are actually consistent with the latest science of EPA, as reflected in the recommendations of the peer consultation panel.** In addition, the EPA peer consultation expert panel recommended that cleavage fragments be treated as any other asbestos fiber of the same morphology and chemical composition.[27]

EPA Region 9 focused on obtaining an accurate count of PCME structures, consistent with our risk assessment protocols and those of Cal/EPA and other health agencies. The counting rules which EPA set for the laboratory were designed to stop counting when a statistically-significant number of PCME fibers were detected. By concentrating on PCME structures, other fiber size classifications may not have been counted to statistical significance. This may have resulted in under counts of other fiber sizes (e.g. the "Berman Crump" protocol fibers referred to in the R. J. Lee Report). **EPA Region 9's study counted PCME structures so that the data could be directly compared to human health epidemiological studies.** These epidemiological studies form the basis for risk assessment models currently used by EPA, Cal/EPA and other federal agencies and international organizations.

**R. J. Lee Report Peer Reviews**

The R. J. Lee Report was reviewed by three individuals, although research of one of the individuals was extensively quoted in the report and therefore the independence of the reviewer is debatable. The three reviewers generally agree with the conclusions of the R. J. Lee Report regarding aluminum content, fiber chemistry, cleavage fragments, and extinction angles.

Both the R. J. Lee Report and one of the reviewers support use of the original "Berman-

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[26]USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page 5-5.

[27]Ibid, page 5-1.

Crump" protocol and calculate a "Berman-Crump" fiber air concentration of 0.0002 fibers/cubic centimeter, using the EPA fibers which they assert meet the "Berman-Crump" definition. The peer reviewer then compares that concentration with an ambient concentration of 0.0008 fibers/milliliter measured in New York City, and states that the "Berman-Crump" value in El Dorado Hills is extremely low. This comparison is flawed for at least two reasons. Significantly, the New York City numbers are based on fibers counted against a totally different size classification (essentially comparing apples to oranges), but **the reviewer also fails to recognize that a concentration of 0.0002 f/cc translates in the protocol to an increased cancer risk of 1 in 1,000 exposed individuals.** This number is disturbingly high and is outside the acceptable cancer risk ranges of EPA, Cal/EPA, and most other state and federal health agencies.

## Conclusions

EPA Region 9 has carefully reviewed the R. J. Lee Report and believes that it makes largely unsupported and incorrect conclusions about the EPA Region 9 El Dorado Hills Naturally Occurring Asbestos Exposure Assessment. EPA Region 9 has asked the United States Geological Survey (USGS) to conduct an independent study of the El Dorado County area to address several mineralogical questions raised by the R. J. Lee Report. The USGS study will use sophisticated analytical techniques (such as electron probe micro analysis) to more completely characterize the naturally occurring asbestos in terms of mineral identification and particle morphology.

All of the EPA Region 9 work in El Dorado Hills was, and continues to be, consistent with the EPA's standard operating and quality control procedures for asbestos work throughout the country.