INTERNATIONAL ENVIRONMENTAL RESEARCH FOUNDATION

Responses by the International Environmental Research Foundation to

Comments by

Human and Ecological Risk Office (HERO)

of the California Department of Toxic Substance Control, April 4, 2011

on

Preliminary Analysis of the Asbestos Exposures
Associated with Motorcycle Riding and Hiking in
The Clear Creek Management Area (CCMA)
San Benito County, California

May 13, 2011

HERO's Introduction

The stated goal: "HERO has reviewed this document with the emphasis on those aspects that affect the risk to human health" (p 1).

According to the IERF report, "it had rained shortly before … but not on the sampling days" (p 2).

Response: The sampling date was selected without any consideration for the weather condition. The report issued by Region 9 of the EPA indicated that under any condition except "actively raining" the asbestos exposure at CCMA would be "of concern". There was no rain during our sample days on April 22 and 23, 2010. The conditions ranged from partly sunny to clear. These weather conditions gave us the opportunity to test the EPA's "of concern" hypothesis.

"In addition to the fiber counts for the health risk assessment (>= 5 µm in length), many more fibers <5 µm in length were found: total of 20 tremolite fragments <5 µm in length (mean length 8.2 µm and mean width 0.75 µm; and 250 chrysotile fragments" (p 2).

Response: In Table 5 of our report (on page 15) the tremolite is described as fragments. The chrysotile is described as chrysotile fibers—not chrysotile fragments as reported by HERO. We cannot recall anyone ever using the phrase "chrysotile fragment."

HERO makes an incorrect correlation. In our report, IERF gives a mean length and width of 8.2 µm and 0.75 µm, respectively, for 12 tremolite fibers that are greater than or equal to a 5 µm length (see Point 6 on page 16 of our report). All risk assessments for asbestos-related cancer rely only on the particles with lengths of 5 µm or greater for determining the cumulative asbestos exposure. This has been the index fiber dimension standard since to establishment of the OSHA-NIOSH asbestos standard on August 27, 1971.

HERO's Specific Comments

1. Concerns regarding hazard identification.

    a. Amphibole asbestos: The authors question the identification of amphibole asbestos at CCMA. They found almost 50% of all fibers to be acicular tremolite fragments (12 of 25 fibers), but no fiber bundles were found (which is inconsistent with tremolite asbestos). However, tremolite was identified based on energy dispersive spectra and this is consistent with previous analyses of CCMA asbestos types.

    Response: Polyfilamentous fiber bundles are consistently found with tremolite asbestos and none was identified in any of the airborne tremolite fragments at CCMA.

    The tremolite fragments at CCMA had energy dispersive spectra similar to tremolite.

    The fragments were too thick to produce selected area electron diffraction (SAED) patterns. Tremolite asbestos is often thin enough to produce diffraction patterns. SAED patterns are required to show the tremolite fragments are amphiboles.

To date there is no evidence of the existence of fiber bundles at CCMA with elemental compositions and SAED patterns consistent with any type of amphibole asbestos. Without this evidence there is no scientific foundation for claiming the presence of amphibole asbestos.

2. Concerns regarding exposure conditions

   a. Weather Conditions: The weather conditions are not representative of regular exposure at CCMA (wet, saturated ground, standing water, and surface water on the road visible in Figure 3; rain in the day before (p 4).

   Response: The small amount of "surface water on the road visible in Figure 3" does not support a claim by HERO of "wet, saturated ground water" as a review of the other photographs in our report clearly illustrate.

   Our sampling dates were selected independent of any knowledge of pending or preceding weather conditions. The 2008 EPA Region 9 report on CCMA claims that airborne asbestos concentrations at CCMA are not reduced to acceptable levels under any weather condition other than "actively raining." Our study proves otherwise.

   b. Exposure Scenarios: Only motorcycle, hiking and "pick-up truck outside air" scenarios were sampled; (not ATV; or air inside SUV vehicles) (p 4).

   Response: We selected to study the exposures of motorcycle riders based on Cooper et al. 1979 reporting they represented the highest asbestos exposures measured. Our expectation is that other vehicle exposures would be similar or lower and hikers would be lower still.

   c. Sampling Conditions: The conditions under which sampling occurred were not well defined (was the pick-up truck moving, how long was the drive or the hike). Is a sampling volume of 85 mL for the pick-up truck scenario really representative of a regular exposure of a park ranger?

   Response: The pick-up truck was moving and parking like one would expect a park ranger on patrol to do.

   The length of the drive or hike would not affect to the exposure intensity. If it is a dusty drive or hike, the length of the drive or hike only defines the length of the exposure, not the exposure intensity.

   The total volume of air sampled to estimate the park ranger's asbestos exposure was not 85mL, but 91,000mL.

   The number of fibers present in 85mL was determined to estimate the exposure.

   For this air sample no fibers >=5µm in length were found. If one fiber were found in 85mL of air, the exposure would be 0.011f/mL.

   For the park ranger/truck sample on this day the exposure was less than the instrument detection limit for the air sample, which was 0.011f/mL. The current OSHA permissible

exposure limit (PEL) for asbestos is 0.1f/mL. The park ranger/truck sample exposure is more than 8.5-fold lower than the OSHA PEL.

To the extent that the air sample collected outside the pick-up truck is representative of the park ranger, it is an accurate estimate of asbestos exposure.

d. Missing laboratory data: Quality Assurance and Quality Control data and laboratory reports for the air sampling were not provided: field blanks, laboratory blank (two control samples are listed in Table 5, but what type of controls is not explained); personal pump calibration; air flow rates; is total volume sampled identical to the "milliliter s of air scanned" in Table 5 (p 4).

Response: Drs. Arthur M. Langer and Robert P. Nolan analyzed all of the air samples themselves. Quality Assurance and Quality Control data include a large collection of tremolite samples with varying morphology collected from human exposures leading to mesothelioma and experimental animal studies where tremolite has and has not caused increased risk of cancer.

We have catalogued reference energy dispersive spectra and selected area electron diffraction patterns representing all the regulated asbestos minerals.

The two air samples labeled as Control-1 and Control-2 in Table 5 are field blanks. These two sample collection cassettes are from the same group of air samples used to collect the personal and area samples. The controls were taken into the field and opened and closed.

The personal pumps were calibrated the evening prior to use in California and the calibration was checked each sample day.

The milliliters of air scanned were not the total volume of air collected. The volume of air sampled ranged from 71,000 to 416,000mL of air at CCMA. In total 2,596,000mL of air was collected in thirteen air samples in the CCMA over two days.

Drs Langer and Nolan have been collecting and analyzing asbestos air sample for more than 30 years.

e. Asbestos analysis: What analytical method was used (Appendix 1 lists the NIOSH-7400 Method, but it was not mentioned in the text); fibers "5 µm or longer" were counted, but it is not clear if the that is identical to the PCME counts from EPA; fiber counts of blank filters; fiber density (f/mm^2); detection limits; calculations for the fiber concentration in the air are not presented (p 5).

Response: The counting criteria from the NIOSH-7400 method was used – objects >=5 µm in length were measured.

To maximize the asbestos exposures IERF counted all the fibers greater than >=5 µm visible by ATEM at 20,000x magnification regardless of their width. All the asbestos fibers of any type present are visible using these conditions.

IERF counting criteria did not eliminate fibers with width below the resolution of phase-contrast light microscopy (PCME). To our knowledge the EPA Region 9 methodology has not been validated by counting the fibers present on a single air sample using phase-contrast microscopy and analytical transmission electron microscopy. The proper question is whether or not the PCME data collected by EPA Region 9 conform to the NIOSH-7400 counting method.

We did not express the results in fiber density (f/mm^2) because that approach cannot be used to sub-total the exposures. The amount of air collected on each filter is different so the fiber densities cannot be added to each other, while the fibers in a milliliter of air can be added (see Table 5). This is particularly important when no characterizing low asbestos exposures, i.e. where asbestos fiber is commonly found in the air samples.

For each air sample collected, the detection limit is determined by taking the reciprocal of the milliliters of air scanned.

The fibers on the filter were examined by analytical transmission electron microscopy using the ISO Method for asbestos in ambient air (see ISO10312: 1995 International Standard, Ambient air-Determination of Asbestos fibres – Direct-transfer transmission electron microscopy method).

f. Counting method: HERO is concerned that the counting method used is not fully described, and therefore the concentration of fibers/mL cannot be verified. There are conflicting statements about how the authors arrived at the concentrations of fiber/mL: The footnote to Table 4 reads: "For the motorcycles air samples the total number of fibers counted was divided by the total volume of air sampled…" on page 18 the authors state: "We counted the number of fibers >=5µm in a given area of the filter. By proportion we counted the number of milliliters of air that contained the 24 fibers. The area (in mm^2) of the filter that was analyzed was not given in the study. The reader cannot relate the number of fibers counted per area with the air volume that went through the filter.

Response: The footnote in Table 4 was to introduce the reader to the concept of fibers per milliliter not to explain in detail how the calculation was done. Table 4 is a summary of the results of the air sampling for fibers and total mass of airborne dust.

In seven of the thirteen air samples in Table 4 no fibers were found.

The airborne fiber concentrations are reported as sub-totals.

The concept of the using proportionality is given later on page 18. The cumulative exposures are reported in the units needed for the risk assessment of asbestos-related cancer.

If we had counted all the fibers on the filter and divided by the total volume of air scanned, within statistical error, the result would be the same as the one we reported.

g. Fiber count example (based on Table 5): in the eight air samples from the motorcyclists, a total of 24 fibers (>=5µm) were identified in a total of 1869 mL of air. If every graticule field

of the eight filters were analyzed for fiber, 24 would have been detected in 1869mL: 24 fibers/filter/1869mL=0.0128f/mL or 0.013f/mL. This is the concentration given in the IERF report (page 18, section 7). However, based on common analytical practice, it is very unusual to analyze/count every graticule field (0.00787 mm^2) of a 385 mm^2 filter. More commonly, between 20-100 fields are counted, the fiber density is counted (f/mm^2) based on average fiber count and mean blank field count. The laboratory then calculates the fiber concentration in f/mL based on the fiber density, effective collection area and the air volume sampled. Based on Table 5, only the number of fibers detected is given (fiber <5µm and fibers >=5µm), there is no indication on how many graticule fields were sampled.

Based on the information given HERO cannot verify the calculation of airborne asbestos concentration (f/mL) (p 5).

Response: Table 5 is a detailed summary of the results of the air sample.

The measurements were done using an analytical transmission electron microscopy at 20,000x magnification. A graticule was not used, but rather the area was measured by the size of the grid opening, in this case 110µm by 110µm, and counting the number of fibers in each grid opening.

We agree it is very unusual to count all the fibers on a collection filter and using our methodology it is impossible.

The results in Table 5 are presented to show the cumulative exposures used to calculate estimates for the risk of asbestos-related cancer.

3. Children's exposures were not mentioned.

Response: The weakest and least credible aspect of the Region 9 EPA study at CCMA is the claim that children riding at CCMA had markedly higher asbestos exposures.

Region 9 modeled the children's exposure simply by collecting an additional air sample, in a lower position on an adult rider.

There is no evidence to support a claim that this sampling approach provides any useful information on the asbestos exposure among children riding independently on their own motorcycle.

Our observations of child riders at the Hollister Hills State Vehicular Recreation Area, near Hollister, California, found that children ride smaller motorcycles that are much lighter than an adult's, and the dust raised will be related to the weight on the rear wheel. For some children this force will be much lower than for an adult.

Currently, free ATV training is offered to children, beginning at age six, at California's OHV Parks and elsewhere. If we assume that child riders are between the age of six and seventeen, the weights and height changes in this group. The simple modeling done in the Region 9 EPA report is not adequate to estimate the real asbestos exposure to children.

Currently the question of child exposures riding at CCMA has not been adequately modeled to provide cumulative asbestos exposures for risk assessment. From our preliminary observation and review of the Region 9 EPA report on CCMA, we would expect a range of values similar to the adult riders in the IERF study. Very young riders going slowly on small motorcycles might have exposures similar to hikers.

4. Motorcyclists were instructed to adhere to "safe riding practices", to minimize exposure to dust. The distance of the riders was given as "between 15 to 20 feet"; however the figures show distances to be much greater: between 30 and 50 feet, more likely. This riding practice cannot be assumed for regular CCMA visitors (p 5).

   Response: The IERF study was designed not as a worst case scenario but to research the possible usefulness of safe riding practices. The distance between the riders varied as they start out together and establish a distance.

   Earlier studies, particularly Cooper et al. 1979, have shown under dry conditions motorcycle riding at CCMA caused airborne asbestos level exceeding the current permissible exposure limit for asbestos. Photographs from the Region 9 EPA study show the trailing riders following closely behind the lead rider, almost intentionally staying within the lead rider's dust cloud.

   Questioning motorcycle riders with a long history of riding at CCMA revealed that it is not a common practice for individuals to ride in a lead rider's dust cloud.

   It is common practice for riders to avoid dusty environments and, when it was open, to ride at CCMA when it was not dry, hot, and dusty.

5. Report assumes 8 hr/day and 5 days/year exposure for a motorcycle rider, but this may not be typical for CCMA visitor.

   Response: We based the exposure scenario on discussions with motorcycle riders with long histories of riding in the CCMA. The effects are linear so riding twice as often would double the risk from 0.18 asbestos-related cancer deaths per million lifetimes to 0.36 asbestos-related cancer deaths per million lifetimes. Eight hours in a single day is a long time to ride a motorcycle.

6. Concerns regarding dose response assessment: HERO questions the validity of "using the 4.2 multiplier to convert the environment exposure to occupational exposure" (168 hours per week/40 hours per week=4.2); when comparing the mean exposure concentration of motorcyclists (0.013f/mL) to the Russian Federation standard for ambient air (0.06f/mL) and the WHO background for urban air (<0.001 to 0.1f/mL).

   Response: HERO does not provide a basis for their "question." The motorcycle exposures from riding at CCMA, under the conditions we observed, are at the high end of background exposures in the ambient air. The comparison was provided to illustrate how low the CCMA exposures are relative to other standards and background concentrations.

7. Concerns regarding risk characterization

    a. No uncertainty analysis was provided.

    The asbestos-related cancer risk from the exposures IERF measured at CCMA is very small. The risk analysis was done separately for males and female and for smoker and non-smokers (see below) and age at first exposure for each asbestos-related cancer. Also, the CCMA risks observed and calculated in our report were compared to other known risks and presented in our report.

    b. No non-cancer hazard assessment (neither was this provided by the USEPA)

    Response: No risk assessment has been developed to relate cumulative asbestos exposure with non-malignant respiratory disease. The asbestos exposure reported by IERF for motorcycle riding is not known to cause asbestosis. PTI reached a similar conclusion in their 1992 study of CCMA.

    c. For a comparison to lifetime risk tables (US-EPA, 1986), the author uses the following exposure assumptions: non-smoking adult; first exposure to begin at age 30, 1 year of continuous exposure to 0.000059f/mL. The asbestos concentration at an average exposure of 0.013f/mL (8 hr per day for 5 days per year) over a year long exposure time. HERO is not convinced that this method of exposure assessment is valid to derive different toxicological effects compared to longer term exposure to lower concentrations. Further, HERO questions if the other exposure assumptions are reflective of the regular users of CCMA: age at onset of exposure is likely to be lower than 30 years; non-smoker status cannot be assumed for all users.

    Response: The EPA Table 6-1 and Table 6-2 (from US-EPA, 1986) assume a continuous exposure to 0.01f/mL over various periods of time. The exposure US-EPA (1986) used their risk assessment, 0.01f/mL, is very similar to the 0.013f/mL IERF determined for the motorcyclists. The motorcycle asbestos exposure is not likely to occur over five consecutive days. The CCMA asbestos exposure IERF determined are very low and not remotely similar to exposures that would overload the lung so averaging over a year seems reasonable.

    The asbestos-related cancer risk for a smoker is provided in the same two tables.

    Mesothelioma in the male and female smokers is 17% and 10% less than male and female non-smokers. Large numbers of smokers die sooner than non-smoker so fewer live long enough to develop mesothelioma.

    For male and female smoker the asbestos-related lung cancer risk is 14-fold and 9-fold higher respectively. The IERF lung cancer risk for non-smoking males and females was 0.018 asbestos-related lung cancers per million lifetimes. For smokers it would be 14-fold and 9-fold higher or 0.25 and 0.16 asbestos-related lung cancers per million lifetimes for male and female smoker respectively (See Table 8 in the IERF report). These

asbestos-related lung cancer risks in the smokers are similar to smoking less than one cigarette in a lifetime (see Table 9 in the IERF report).

8. Other concerns: "Percentage of mesothelioma deaths in the US general population" The authors cite a reference (Price B, Ware A, Crit Rev Toxicology 39: 576-588, 2009) that states the percentage of mesothelioma deaths in the US general population to be 0.11%. This number is not supported by the CDC, which gives the mortality rate of the US between 1999 and 2005 as 13.8 per one million population or 0.00138% not age adjusted). In 2007, the Interactive Cancer Atlas of the CDC listed the age-adjusted mortality rate for males and females to be 0.8 per 100,000 (or 8 per million or 0.0008%

   Response: It is not clear that the reviewer fully comprehends Price and Ware (2009) and our comparison. In Section 10 of our study (page 24), the authors inform the reader of the number of mesothelioma deaths, which occur in the United States each year to give the reader perspective on the increase in mesothelioma risk IERF calculated from riding at CCMA.

   We used the data from the National Cancer Institute SEER program. This is the database researchers use to follow the US mesothelioma trends. On average for each year between 1975 and 2005, 2,291 mesothelioma deaths occurred among males and females (see IERF Table 10).

   During that same period, each year, 2,104,290 deaths from all causes were occurring each year. So 2,291mesothelioma deaths/2,104,290 total deaths x 100=0.0109% or 011% of all US deaths between 1975 and 2005 were from mesothelioma.

   HERO claims this calculation "is not supported" by the CDC, and give the mesothelioma rate as 13.8 per million people. That is a comparison using living people. We calculated the percentage of deaths in the general population from mesothelioma—NOT the number mesotheliomas per living persons in the US.

   About 0.8% of the population dies each year, and 0.8% of one million is 8,000.

   Using the CDC number of 13.8 mesothelioma deaths per million people and dividing by 8,000 total deaths, we get 0.17% of all US deaths per year as due to mesothelioma (not age adjusted). If we take the age adjusted rate of 8 mesothelioma deaths/8,000 total deaths=0.10% of all US deaths are from mesothelioma. This is almost identical to what is given in IERF Table 10. The CDC and their interactive cancer atlas support the IERF conclusion and not those of HERO.

   The increase in the mesothelioma risk from the asbestos exposure at CCMA is 0.2 per million or 0.00002% for males and females—well below the 0.11% of deaths in the general population that are attributed to mesothelioma.