NATIONAL STONE, SAND & GRAVEL ASSOCIATION

Natural building blocks for quality of life

May 10, 2007

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Re: Notice - Request for Comments and Additional Information

Dear Dr. Masten:

The National Stone Sand & Gravel Association (NSSGA), the world's largest mining trade association by product volume, is pleased to respond to the National Toxicology Program's request for public comments on the most recent nominations for toxicological study. Our comments pertain specifically to the substances listed in Table 1 of the March 29, 2007 *Federal Register* identified as "Asbestos, naturally occurring and atypical forms" which were nominated by the National Center for Environmental Health, the Agency for Toxic Substances and Disease Registry and the U.S. Environmental Protection Agency.

Toxicological Assessment Challenges Presented by Natural Minerals

Unlike the chemical substances listed in Table 1, asbestos and other asbestiform minerals are natural minerals, which present unique challenges for toxicological assessment. The term asbestos is a commercial term that refers to the following six asbestiform minerals: the serpentine mineral, chrysotile (CAS No. 12001-29-5), and the amphibole asbestiform minerals crocidolite (CAS No. 12001-28-4), grunerite asbestos also called amosite (CAS No. 12172-73-5), anthophyllite asbestos (CAS No. 77536-67-5), tremolite asbestos (CAS No. 77536-68-6) and actinolite asbestos (CAS No. 77536-66-4). The term asbestiform has a specific mineralogical meaning. It refers to the unique way some minerals grow (mineral habit) in nature. Asbestiform minerals grow almost exclusively in one direction and exhibit narrow width (on the order of 0.1 micron). In fact, their width dimension is independent of their length, achieving length to width ratios of 20:1 to 100:1 or higher. Asbestiform fibers that are one micron and wider are composed of bundles of smaller fibers called fibrils. Asbestiform minerals, when pressure is applied,

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show flexibility and will easily separate into fibrils. All six types of asbestos have these asbestiform properties. An attachment to these comments illustrates these properties.

Each type of asbestos has been recognized as a human carcinogen for decades and it is questionable that further study regarding carcinogenic properties is a proper use of resources. The carcinogenicity of asbestos has been demonstrated in cellular, animal toxicity studies and in epidemiological studies of workers. The epidemiological studies that have been used to perform quantitative risk assessments for asbestos involve workers exposed during the manufacture and use of commercial asbestos products. These asbestos products were processed to produce a product that had properties that were deemed beneficial to its many customers (e.g., high fiber length, high flexibility, chemical resistance, high tensile strength, etc.). Most of these studies involved the commercial forms of the asbestos minerals with minor concentrations of nonasbestiform minerals.

Each of these asbestos minerals can be found in the earth in igneous or metamorphic rocks and, to varying amounts, have been produced commercially. When asbestos is encountered in the earth, the exact same mineral in the nonasbestiform habit always, without exception, accompanies it. The nonasbestiform habit, or prismatic variety of these minerals, is composed of the exact same mineral composition but the mineral grew like many common minerals in a multi-directional manner not in a parallel alignment as the asbestiform minerals. When pressure is applied to the nonasbestiform minerals, they shatter forming prismatic particles called cleavage fragments. Some of these fragments are elongated, however, their length is dependent on their width – to be longer, they must also be wider. Cleavage fragments that are ten microns or longer, are rarely thinner than a half a micron in width. Nonasbestiform minerals do not grow in bundles and are not flexible. The nonasbestiform varieties of the asbestos minerals are very common rock forming minerals found throughout the United States (see attached map).

It is important to note that when asbestos is found in the natural environment, it will always be accompanied by its nonasbestiform analog. The converse is rarely true. This is because asbestiform minerals must undergo a unique set of geologic circumstances in order to form the long thin bundles of fibers. There must be mineral-rich fluids associated with metamorphic conditions and open spaces for the long fibers to grow. These conditions are restricted to the upper portions of the earth's crust in environments that contain faults, joints, folds, etc. The nonasbestiform analogs of these asbestos minerals do not need these unique conditions and consequently are common rock minerals found in many areas of the planet.

A sample of "naturally occurring asbestos" therefore will contain both the asbestiform and nonasbestiform varieties of the same mineral and assigning the toxicological outcome in a study to one or the other variety or to both becomes problematic. If the outcome is assigned to both for convenience, then large portions of the U.S. could be designated "toxic" even though those areas may not even contain the asbestiform variety of the mineral. This is a major concern of the NSSGA as well as others who work with the earth (i.e. construction, land development, homeowners, real estate, farming, etc.). It is critical to properly assign the toxicological result to the responsible agent.

The task is not easy. Even the National Institute of Standards and Technology (NIST), as is noted on the certificate enclosed with each reference standard produced, has asbestos standards for laboratory reference analysis that are contaminated with up to twenty percent of the nonasbestiform variety of the asbestos mineral. There are some that would say that if the nonasbestiform variety of the same mineral existed in the same dimensions as the asbestiform variety, then they should be viewed the same. We would agree, however, they do not exist in the same dimensions. A bundle of fibers that is one micron wide and a cleavage fragment that is one-micron wide, present completely different challenges to the organism that is exposed. In the asbestiform habit, the bundles will disaggregate in the lung and present a significantly different exposure than the single cleavage fragment, which will not separate into smaller and smaller particles. Preparing and characterizing samples for toxicological testing to account for this spectrum of different morphologies of the minerals is the most important aspect of the entire effort. The scientific literature regarding the health impact of exposure to asbestiform minerals, mixed asbestiform and nonasbestiform and only nonasbestiform minerals clearly show there is a difference that is related to the mineral growth habit of the mineral.

Morphological Differences in Minerals Show Different Health Effects

The NSSGA has studied the health effects of asbestiform and nonasbestiform minerals for over 20 years. Most recently (2005) the NSSGA commissioned comprehensive reviews of the literature on these mineral habits with respect to *in vitro*, *in vivo* and relevant epidemiological studies to contrast the differences if any. The following is a summary of these reviews. The papers have been accepted for publication and are included as attachments to these comments.

Cellular Toxicology – *In Vitro Studies*

There are twenty-four *in vitro* studies or reviews of the science that contrast the toxicological outcome between the asbestiform and nonasbestiform habits of the same minerals. Most of these studies involve chrysotile and its nonasbestiform counterpart, antigorite, crocidolite and its nonasbestiform counterpart, riebeckite and amosite and its nonasbestiform counterpart, cummingtonite-grunerite. These studies were conducted in a variety of species and cell types including hamster tracheal explants, hamster tracheal epithelial cells, rat lung epithelial cells, rat and hamster alveolar macrophages, rat pleural mesothelial cells, sheep red blood cells, and Chinese hamster ovary cells. All of these studies clearly show a difference between the nonasbestiform and asbestiform habits of the same minerals.

Animal Toxicology – *In Vivo Studies*

There are ten *in vivo* studies that also demonstrate significant differences in toxicological outcome (tumor generation) between the two mineral habits of the same mineral. Most of these studies used tremolite asbestos and nonasbestiform tremolite, ferro-actinolite asbestos and nonasbestiform actinolite under various exposure routes including inhalation, intrapleural injection, intrapleural implantation or intratracheal instillation in either rats or hamsters. As in the *in vitro* studies, clear differences are seen between the two mineral habits. Samples with the asbestiform or mixed asbestiform/nonasbestiform mineral habits caused tumors while the nonasbestiform variety of the same minerals did not.

Epidemiological Studies

There are three groups of workers who have been exposed to the nonasbestiform amphiboles, cummingtonite-grunerite (Homestake Gold miners and Minnesota Taconite miners) and nonasbestiform tremolite and anthophyllite (New York Tremolitic Talc miners). Each has at least two or more separate epidemiological studies published in the literature. When these epidemiological studies are contrasted with cohorts that were exposed to either amosite asbestos (asbestiform cummingtonite-grunerite) or tremolite asbestos, the differences again are very clear. The tremolitic talc mine has 50 - 60 percent nonasbestiform tremolite in the deposit, while the Libby, Montana vermiculite mine had only 4-6 % asbestiform amphibole. The health outcomes of both are very different.

The consistency of these health findings in cellular, animal and human studies are very striking and should be very informative to the NTP. We would expect similar findings for other asbestiform and nonasbestiform habits of the same mineral that are not currently regulated as asbestos. Again, we caution that any study conducted needs to account completely for the morphology of the minerals being tested and that toxicological outcomes be specifically assigned.

<u>Regulatory History Regarding Asbestiform and Nonasbestiform Minerals</u>

The issue of whether to treat both habits of the asbestos minerals equally has been dealt with several times over the past 20 years by several federal agencies and departments. The Occupational Safety and Health Administration (OSHA) promulgated its asbestos standard in 1986 and specifically included the nonasbestiform habits of actinolite, tremolite and anthophyllite. This decision by OSHA was challenged and administratively stayed until a comprehensive review of the science was performed. In 1992, OSHA removed the nonasbestiform minerals from the standard stating that the minerals did not present asbestos-like hazards. In 1988, the Consumer Products Safety Commission (CPSC) ruled that the nonasbestiform tremolite in play sand was not a hazard like tremolite asbestos. The most recent CPSC decision in this area dealt with tremolite cleavage fragments in crayons. The Commission reaffirmed its early decision regarding nonasbestiform tremolite. The Mine Safety and Health Administration (MSHA) has consistently stated that it is not intent on regulating the nonasbestiform minerals as if they were asbestos with its latest statement made with its proposed asbestos standard in 2005. Only NIOSH has advocated that cleavage fragments of the asbestos minerals that fit the simplistic counting criteria (fibers longer than 5 microns with a minimum length to width aspect ratio of 3 to 1) in its asbestos analytical method be treated and designated as asbestos. The counting criteria in these analytical methods were designed for measuring commercial asbestos exposures and not asbestos in a mixed dust environment. To no avail, NIOSH has been asked numerous times to provide the scientific basis or studies it relies upon for this position.

<u>Need for Additional Toxicological Studies</u>

The NSSGA believes that the existing scientific literature is ample to toxicologically distinguish the nonasbestiform minerals from their asbestiform counterparts. The NSSGA believes, and has testified to MSHA and others, that **all asbestiform amphiboles** (defined mineralogically) be treated as if they present an asbestos risk. However, we are extremely concerned that common, nonasbestiform, rock forming minerals, that have asbestiform counterparts, will be labeled improperly as asbestos creating enormous problems for the many businesses and people that live upon the earth and come into contact with these ubiquitous minerals.

If NTP decides to proceed, we caution the NTP to carefully and comprehensively characterize the mineralogy of any samples used in this effort.

Sincerely,

[Redacted]

William C. Ford, P.E.
Senior Vice President

Attachments:

1. Photographs – Asbestos and Nonasbestiform Rocks
2. Characteristics of asbestiform and nonasbestiform minerals
3. Map – Igneous and Metamorphic Rock Distribution
4. *Assessment of the Pathogenic Potential of Asbestiform vs. Nonasbestiform Particulates (Cleavage Fragments) in In Vitro (Cell or Organ Culture) Models and Bioassays* – Brooke T. Mossman, Ph.D.
5. *A Review of Carcinogenicity Studies of Asbestos and Non-Asbestos Tremolite and Other Amphiboles* – Mr. John Addison and Ernest E. McConnell, D.V.M.
6. *An Evaluation of the Risks of Lung Cancer and Mesothelioma from Exposure to Amphibole Cleavage Fragments* – John F. Gamble, Ph.D. and Graham W. Gibbs, Ph.D.
7. *The Asbestiform and Prismatic Mineral Growth Habit and Their Relationship to Cancer Studies*