Georgia-Pacific Gypsum LLC
133 Peachtree Street, NE
8th Floor
Atlanta, GA 30303
(404) 652-5155
(404-749-2685 fax
drfleine@gapac.com

David R. Fleiner
President, Gypsum Division

Via email: nioshdocket@cdc.gov

NIOSH Mineral Fibers Work Group

Subject: Comments on NIOSH Document—Asbestos and Other Mineral Fibers: A Roadmap for Scientific Research
NIOSH Docket Number NIOSH-099

To Whom It May Concern:

Georgia-Pacific has reviewed the subject NIOSH document that was released for comment in February 2007. We applaud NIOSH for undertaking an evaluation with regard to research needs to understand the potential health effects associated with human exposures to mineral fibers, and fully agree with the goal of developing "evidence-based public health policies for asbestos and other mineral fibers" as set forth in the foreword to the document. While we concur with many aspects of the proposed strategy, we also have comments regarding some specific issues, and have identified areas that are, in our opinion, in need of clarification. These comments are provided below.

The Roadmap should not lump all asbestos together when evaluating potential associations with health effects

Extensive research conducted in the last 20 years has clearly established that the toxicity of asbestos fibers is dependent on both fiber type and fiber size. This has become clear from detailed evaluations of epidemiological studies and exposure reconstruction. Our understanding of the reasons for the differential toxicity of different fiber types has subsequently been substantiated by supporting research using animal models. Earlier evaluations that lacked the sophistication of assessing specific mineral types and fiber sizes served to complicate the understanding of the factors controlling the toxicity of asbestos. As written, the Roadmap appears to lump all asbestos together with regard to association with health effects:

- The Roadmap contains statements such as "mineral fibers that grow in asbestiform habits are clearly of health concern, and there is controversy about whether [other fibers] are as hazardous as asbestos." These types of statements ignore the fact that there is still considerable discussion regarding variable toxicity associated with different types of asbestos.

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- Statements such as "the association of mesothelioma deaths with industries and occupations known to involve asbestos exposure is apparent...." perpetuate the failure to discriminate between fiber types with regard to toxicity, and belie any discussion in this document or intent to develop research to better elucidate variable toxicity (and controls thereon) of different types of asbestos fibers.

The strategic research defined or directed by the Roadmap needs to account for the fact that more work is needed to better elucidate between different types of asbestos fibers with regard to human toxicity. The Roadmap needs a section specifically targeted at discussing what is currently known/understood about the differential toxicities of the different asbestos fibers, and then proceed to identify strategic areas where additional information is required. Discussion of non-asbestiform mineral fibers would need to be addressed in separate sections of the document.

The "Roadmap" ignores existing risk assessment protocols for asbestos.

We believe that NIOSH should take into account the substantial effort already undertaken by EPA in revising its asbestos risk assessment protocol. Specifically, based on an extensive analysis of the animal toxicology and human epidemiological data, of which only a very small portion is discussed by NIOSH, Berman and Crump (2003) have proposed that carcinogenic potency be evaluated based on fibers >10 μm in length and <0.4 μm in width. The Berman and Crump method also acknowledges that carcinogenic potency also differs depending on fiber type. For mesothelioma, the proposed potency assigned to chrysotile fibers is between two and three orders of magnitude lower than for amphibole fibers, whereas for lung cancer the proposed potency of chrysotile fibers is between one fourth and one fifth of that for amphiboles. A 2003 peer-review panel strongly endorsed this conceptual approach, but recommended additional research be conducted to refine details (Eastern Research Group 2003); this additional research should be considered, if not directly supported, by NIOSH.

Reliance on results from long-term animal studies is misguided.

We believe that great caution should be taken when recommending the use of long-term animal studies, as presented in Section 2.4.2.2 of the Roadmap. Long-term studies in animals are unlikely to provide information that is useful for understanding the human experience with regard to health effects associated with exposure to fibers. As touched upon in the Roadmap, it is unclear whether there is a good animal model for human toxicity of fibers. Even if a model can be validated for one type of fiber (e.g., chrysotile, as suggested in the Roadmap), there is no firm scientific basis upon which to assume that the same model will provide relevant information for other fiber types. There may be differences in the deposition of fibers in the lungs of different species, and there may be anatomical and physiological differences in the mechanisms and

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processes that result in clearance of fibers from lungs across different species. For example, if macrophages are involved in lung clearance of mineral fibers or cleavage fragments, the size or volume of macrophages in rodents may impose limitations on clearance that would not be experienced in the human lung. Certainly, more animal studies conducted at high exposure doses cannot be expected to result in data that are relevant to human exposures to mineral fibers. Numerous animal studies have already been conducted to assess the toxicity of chrysotile, and none emerge as a useful predictive model for human toxicity. We agree that *in vitro* and short-term *in vivo* bioassays can provide supplemental information to assist in understanding what is happening in the human experience. For example, once results from epidemiological studies demonstrated the difference in carcinogenic potency with fiber type and fiber size, subsequent biopersistence and in vitro studies have helped elucidate the potential mechanisms influencing the health effects. Once correlated back to the human experience, these short-term and in vitro methods may provide a useful predictive tool for understanding the factors that control human toxicity from exposure to fibers. While we encourage NIOSH to consider the recent work conducted by Bernstein et al. (2003a and b; 2004; 2005a and b; 2006) in developing their future research plans in this area, it is important that NIOSH not aim to place long-term animal studies in a primary role with regard to understanding the human experience from exposures to fibers.

Roadmap fails to acknowledge full potential from existing analytical methods.

Section 2.2 of the Roadmap provides a discussion of the need for better analytical methods to provide improved resolution. We believe that this remains part of the identified needs in the Roadmap only because the earlier sections of the document do not fully discuss existing capabilities. Specifically, although TEM methods are discussed in Section 1.2 of the Roadmap, the discussion is limited to only certain applications of TEM (i.e., Method 7402). Other methods (e.g., ISO 10312) and/or supplementary techniques (e.g., energy dispersive x-ray analysis) are capable of providing the kind of data (with regard to finer fibers and discriminating mineral types) that the Roadmap indicates is lacking. In the absence of more efficient and less expensive methods, it is important that NIOSH acknowledge that effective methods are available to provide adequate characterization of mineral fibers, and that at this point in time, a comprehensive program can provide adequate data for understanding the nature of fiber exposures.

Summary

While Georgia-Pacific supports the goal of developing an evidenced-based policy regarding the health effects of asbestos and other mineral fibers, we also believe that it is important that the Roadmap be very clear about what information does or does not exist with regard to understanding exposure and potential toxicity associated with mineral fibers, particularly

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asbestos. The primary points we believe need to be addressed in a revised Roadmap are to better articulate what is currently known about the differential toxicities of different fiber types and fiber sizes of asbestos, and to acknowledge the extensive efforts to date to develop risk assessment methods that account for these differences. In doing so, NIOSH will help ensure that future methods for assessing potential health risks associated with exposure to other mineral types will build off of our existing understanding of asbestos toxicity. Finally, it is important that NIOSH acknowledge the analytical capabilities that currently exist for evaluating and characterizing exposures to fibers, while attempting to validate more efficient and inexpensive analytical techniques.

Thank you for this opportunity to comment.

Sincerely,

Dave Fleiner
President, Gypsum Division