



April 24, 2012

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Dear Drs. DeVoney and Wong:

Thank you for this opportunity to point out concerns with the scientific basis of EPA's draft Integrated Risk Information System (IRIS) assessment of Libby Amphibole (LA) Asbestos, and the policy and practical implications that arise if the shortcomings of the scientific analysis are not corrected.

We submit these public comments pursuant in part to the notification at 77 FR 18808, March 28, 2012, for consideration by EPA's federal advisory committees and panels. Please place a copy of these comments in all appropriate dockets and hands.

The undersigned members are an informal group of allied national organizations representing a broad spectrum of industry and business activity with an interest in assuring that government agencies utilize sound science and feasible recommendations in policy and regulatory development. We agree with banning the deliberate addition of true asbestos in the manufacture of products made or used in the United States. We agree

that great care must be taken to define and differentiate asbestos and asbestiform minerals in the man-made as well as the natural environment from other minerals that do not cause risk of asbestos-related disease. We agree that tolerance levels should be based on valid risk assessments and must be technically feasible to achieve.

Our comments relate to the 500-page EPA draft document (“EPA draft”) dated August, 2011, titled *Toxicological Review of Libby Amphibole Asbestos*.

Specifically, our concerns are based in part on the numerous criticisms of the EPA draft made public by a variety of scientists inside and outside the federal government, including members of the Science Advisory Board (SAB) LA Review Panel. There is significant concern within the scientific community on a number of issues, particularly that the LA reference concentration (RfC¹) was inexpertly derived.

These scientists recommend that EPA take specific steps to address procedural and technical deficiencies in its draft before it is finalized.

Many of the scientists’ criticisms deal with highly technical aspects of noninfectious-disease epidemiology and risk assessment methodologies that are outside the scope of our members’ normal business activities. However, the assessment has obvious and practical consequences and implications that require no special expertise to appreciate and that must be addressed:

- The proposed RfC value (0.00002 f/cc) for localized pleural thickening (LPT²) is well below the ambient airborne concentration of asbestos fibers in many parts of the country—a fact pointed out by reviewers from the U.S. Centers for Disease Control and Prevention (CDC) Agency for Toxic Studies and Disease Registry (ATSDR). EPA appears to have ignored this caution. As the reviewers pointed out, the proposed RfC is biologically implausible: there would be an epidemic of LPT in many parts of the country if the RfC value was remotely realistic, but as yet EPA has provided no evidence that any such epidemic exists or is anticipated. We believe that the RfC should be scientifically validated by comparison with the experiences of other cohorts similarly exposed to LA.

It appears that the IRIS program has neglected to use consistent and transparent protocols for the conduct of evidence-based study reviews and has not followed National Academy of Sciences (NAS) recommendations for causal inference. In particular, the NAS formaldehyde panel previously admonished EPA to avoid using “parameters that yield results that are biologically implausible or inconsistent with the

¹ The RfC is an estimate of a continuous inhalation exposure concentration to people, including sensitive subgroups, that is likely to be without risk of deleterious effects during a 70-year lifetime. Notably, this is the first published RfC by EPA that defines a non-cancer endpoint as the deleterious effect.

² LPT is a nonmalignant (i.e., non-cancerous) accumulation of fibrous tissue on the surfaces of the pleura (the pleura are tissues that line the inside of the chest cavity and adjacent, exterior surface of the lungs). Pleural thickening can be caused by exposure to asbestos; however, as EPA notes in the draft, the background prevalence of pleural thickening in unexposed populations is largely unknown. EPA selected an LPT background prevalence of 1% for their analysis.

available data.” Yet, EPA appears to have done so again by proposing an RfC value of 0.00002 f/cc. We believe that EPA should consider other exposure endpoints and modeling approaches in deriving a biologically plausible RfC.

- The proposed RfC is unrealistic because it is virtually impossible to assess compliance with it. From both a technical and economic perspective it is not feasible to measure fiber concentrations at the RfC level. This fact was similarly pointed out to EPA by ATSDR reviewers. EPA appears to have again ignored the ATSDR’s caution. We believe that EPA should consider the technical and economic considerations and implications of the RfC. Since the RfC is less than the existing ambient asbestos concentrations in parts of Libby, Mont., that have already been remediated, would EPA propose wholesale relocation of Libby residents in order to meet the proposed RfC limit?
- The RfC will almost certainly be (mis)used as a *de facto* limit for exposure to ambient amphibole asbestos and nonasbestiform amphiboles alike. For example, the RfC could be invoked (naively or otherwise) to block virtually any commercial, recreational, or other activity in many parts of the country.

Though minor by comparison, virtually all reviewers agreed that the draft was poorly edited, contained internal inconsistencies, lacked an executive summary, and was arranged in a fashion that stymies attempts to find pertinent information. These problems are reminiscent of those that prompted the NAS to devote an entire chapter of the peer review of the IRIS formaldehyde assessment—and raise additional concern that the Agency’s efforts to address that report have not been effective.

Finally, in response to recommendations—including those from SAB Review Board members—that EPA take time to improve the draft technically before it is finalized, an agency representative stated in February 2012 that, “it is important to get something done on Libby without opening [the door to] broader controversy.” We believe that EPA should take the time to get the science right and not rush the process just “to get something done,” particularly when the result is neither realistic nor achievable.

We encourage EPA to seek additional stakeholder review and input following changes made to address reviewer comments. We believe it is critical that the IRIS program rely on the highest quality, most reliable science, and that the program continue to take the steps necessary to improve the scientific validity and usefulness of IRIS assessments.

Danielle DeVoney, PhD / Diane Wong, PhD / US EPA / NCEA / LA SAB / 24 April 2012

Thank you for the opportunity to provide these comments.

Sincerely,

American Chemistry Council
American Road & Transportation Builders Association
Associated Equipment Distributors
Association of Equipment Manufacturers
Associated General Contractors
Industrial Minerals Association - North America
National Association of Manufacturers
National Mining Association
National Stone, Sand & Gravel Association
U.S. Chamber of Commerce

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