AMERICAN PUBLIC HEALTH ASSOCIATION
For science. For action. For health.

August 10, 2018

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Problem Formulation Document on Asbestos
Docket ID #: EPA-HQ-OPPT-2016-0736

Dear Acting Administrator Wheeler:

On behalf of the American Public Health Association, a diverse community of public health professionals that champions the health of all people and communities, I write to provide comments on EPA's "Problem Formulation of the Risk Evaluation for Asbestos."

In 2009, APHA adopted a policy statement calling for the elimination of asbestos. APHA supports the adoption of a ban on the manufacture, sale, export, and import of asbestos and asbestos-containing products, as well as policies to ensure that asbestos-containing materials (e.g., in homes and buildings) be identified and managed to eliminate exposure.[1] The 2016 amendments to the Toxic Substances Control Act provide the best opportunity in decades to address the significant risk of malignant and non-malignant disease for individuals who are exposed to asbestos. Unless amended, EPA's problem formulation for asbestos will result in a risk evaluation that fails to accomplish these public health goals.

Our comments address seven issues in the "Problem Formulation of the Risk Evaluation for Asbestos."

Problem Formulation Process

Before the problem formulation process begins, interested parties need a thorough assessment of the magnitude of the problem. That step precedes the deliberations with stakeholders on how to define the problem. The way the problem is framed---its depth and breadth---determines the ways the risk is analyzed and ultimately managed.[2]

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[1] American Public Health Association. Policy Statement No. 20096: Elimination of Asbestos.
[2] National Research Council. Understanding Risk: Informing Decisions in a Democratic Society. Washington DC: National Academy Press, 1996.

EPA's scoping and problem formulation process circumvented this critical first step. The agency's problem formulation "put the cart before the horse." The agency fails to present a quantitative assessment of the environments and materials to which U.S. residents are potentially exposed to asbestos. This information is essential in order to make decisions about the problem (or problems) that will be addressed in a risk assessment.

EPA indicates that "the Agency's focus is on the conditions of use that raise the greatest potential for risk."[3] However, without first identifying and estimating the universe of potential exposures to asbestos, it is not possible for EPA to determine the greatest potential for risk. As a result, the Problem Formulation of the Risk Evaluation for Asbestos has defined the problem in an extremely narrow way.

Thirty years ago, EPA's comprehensive risk analysis on asbestos established the foundation for the regulation that would have phased-out nearly all use of asbestos. Today, the evidence of adverse health effects from exposure to asbestos is even more robust. There is no safe level of exposure.

As noted by the World Health Organization:

"Bearing in mind that there is no evidence for a threshold for the carcinogenic effect of asbestos, including chrysotile, and that increased cancer risks have been observed in populations exposed to very low levels, the most efficient way to eliminate asbestos-related diseases is to stop using all types of asbestos."[4]

It is not necessary for EPA to revisit the unit risk. The health risks associated with exposure to asbestos have been peer reviewed and thoroughly examined by many expert bodies, including the International Agency for Research on Cancer and the Occupational Safety and Health Administration. Asbestos presents an unreasonable risk of injury and all use should be banned permanently.

Exclusion of Legacy Uses of Asbestos

APHA disagrees with EPA's decision to exclude from its problem formulation the risk of asbestos exposure from legacy uses. EPA describes legacy uses as:

"asbestos-containing materials that remain in older buildings or are part of older products but for which manufacture, processing and distribution in commerce are not currently intended, known or reasonably foreseen."[3]

It is, in fact, these legacy uses that put the greatest number of U.S. residents at risk of exposure to asbestos.

[3] EPA. Problem Formulation of the Risk Evaluation for Asbestos, May 2018. (p.9)
[4] World Health Organization (2014). Chrysotile Asbestos.
http://www.who.int/ipcs/assessment/public_health/chrysotile_asbestos_summary.pdf

EPA fails in its problem formulation, for example, to make any estimate of the number of buildings that contain asbestos and thus the number of individuals potentially exposed. Using potential asbestos exposure in housing to illustrate, the most recent data from the U.S. Census Bureau's American Housing Survey indicates that 40 percent of the nation's 118 million housing units (i.e., 47.2 million) were built before 1970. EPA's Office of Land and Emergency Management notes that residential structures built before 1975 "may contain significant amounts of asbestos" and even "structures built after 1975 may also contain asbestos."[5,6,7] The asbestos-containing materials found in homes includes roof shingles; attic insulation; floor tiles; drywall joint compound; water heater insulation; and wiring insulation. Using this data and that from other sources, EPA should estimate the number of U.S. housing units that contain asbestos, as well as the number of potential exposed individuals, including "potentially susceptible or exposed subpopulations."

We agree with EPA that even when asbestos is contained in a product or article, it has the potential to become friable.[8] This risk is particularly high when homeowners, maintenance or repair workers perform tasks that may disturb the asbestos-containing material (ACM). EPA should also use data from the American Housing Survey to estimate the annual number of renovations, repairs and remodeling in which ACM may be encountered.

Similarly, EPA should estimate the number of schools and public buildings that contain asbestos. The most recent estimate of school buildings with asbestos-containing materials was made by EPA more than 30 years ago.[9] At the time, more than 35 percent of schools were found to have asbestos. Data from the U.S. Department of Education's National Center for Education Statistics could help inform a new estimate.

NCES reports that the average number of years since construction of all U.S. public schools is 40 years.[10] Given the age of many schools, some portion of these structures have asbestos-containing materials. Data from NCES and other source could assist EPA in making an estimate of the number. Recent investigations by journalists, including those at *The Detroit Free Press* and *The Philadelphia Inquirer* illustrate the ways in which students, teachers, and staff are exposed to asbestos-containing materials.[11,12]

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[5] Hurricane Katrina: EPA's current and future environmental protection efforts could be enhanced by addressing issues and challenges faced on the Gulf Coast. June 2007, https://www.gao.gov/assets/270/262716.pdf

[6] EPA. Dealing with Debris and Damaged Buildings. https://archive.epa.gov/katrina/web/html/debris.html#Asbestos

[7] In some U.S. cities, the percent of housing built prior to 1970 is substantial. According to the American Housing Survey, (2015 National, General Housing Data: All Occupied Units), the percentage of housing that fits this category in Pittsburgh, PA is 67 percent; in Rochester, NY and Philadelphia, PA it is 59 percent; in Detroit, MI it is 54 percent; and in Chicago, IL it is 53 percent.

[8] 83 Federal Register 26925 (June 11, 2018).

[9] EPA. Evaluation of the Asbestos-in-Schools Identification and Notification Rule. Report No. 560/5-84-005. October 1984.

[10] U.S. Department of Education. Condition of America's Public School Facilities: 2012-2013. Report No. NCES 2014-022.

[11] J. Dixon and K. Tanner. "Deadly asbestos: workers put in jeopardy, but state won't get tough." *Detroit Free Press*, April 30, 2016; J. Dixon. "Asbestos contractors target homeless, other vulnerable people."

APHA disagrees with EPA's determination that the exposures to asbestos that are occurring in homes, schools and other buildings are not current conditions of use. As Brent Kynoch, managing director of the Environmental Information Association, wrote in March 2018 comments to EPA:

"Every time a maintenance worker strips and waxes an asbestos tile floor, every time an electrician moves a ceiling tile in a building with spray-applied asbestos fireproofing, and every time an HVAC technician enters a boiler room with asbestos-containing insulation, these materials are being 'used' and create the potential for unprotected exposure to both these workers and others in the building.

The 'use' of the material does not end at the time of manufacture or installation. For many of these materials, the 'use' only begins at installation. Most certainly, building 'users' are at risk of asbestos exposure from installed legacy asbestos-containing materials caused by vibration, air erosion, water damage and inadvertent or accidental physical contact by citizens and tradesmen."[13]

The Frank R. Lautenberg Chemical Safety for the 21st Century Act instructs EPA to address unreasonable risks from the use and disposal of chemical substances. That is, the ongoing uses in homes, schools, and buildings. We disagree with EPA's interpretation that the statute applies to "uses for which manufacture, processing or distribution is intended, known to be occurring, or reasonably foreseen." EPA is using this incorrect interpretation to justify its decision not to "reach back to evaluate the risks associated with legacy uses."[14]

Disease Risk Associated with Legacy Uses of Asbestos

Malignant mesothelioma (MM), lung cancer, and other cancers from exposure to asbestos typically occur 20 to 40 years following a person's first exposure to asbestos. There were more than 45,200 MM deaths in the U.S. from 1999 through 2015. Nearly 2,500 of those deaths were individuals aged 35-54 years.[15] Deaths in this age group (and among those younger than 35 years) are particularly relevant to illustrate why EPA should not exclude legacy uses from its problem formulation.

By the early 1980's, the production of asbestos-containing products had declined substantially in the U.S. Accepting EPA's characterization of legacy uses, exposure to legacy uses began in the mid-1980s. The MM deaths during 1999 through 2015, particularly those among individuals age 35-54 years, came from exposure to legacy uses of asbestos.

Detroit Free Press, May 1, 2016. J. Dixon. "Dearborn Heights janitor says she's vindicated by OSHA." *Detroit Free Press*, June 30, 2016.

[12] W. Ruderman, B. Laker, and D. Purcell, "Hidden peril," *The Philadelphia Inquirer*, May 10, 2018

[13] Brent Kynoch. Unafe Exposure to Asbestos from Installed Asbestos-Containing Building Materials, March 2018. EPA-HQ-OPPT-2016-0736-0123.

[14] EPA. Problem Formulation of the Risk Evaluation for Asbestos, May 2018. (p.9)

[15] Mazurek JM, Syamlal G, et al. Malignant Mesothelioma Mortality - United States, 1999-2015. MMWR Morb Mortal Wkly Rep. 2017 Mar 3;66(8):214-218.

One can also look at the most recent death certificate data for MM (the tip of the iceberg for asbestos-related cancers) to illustrate the disease risk from legacy uses of asbestos. Table 1 provides data on MM deaths by age of decedent in the years 2010 through 2014 (the most recently available data.)[16]

Year of Death	***Malignant Mesothelioma Deaths, Any Site, U.S. Residents, Age at Death***						
	15-24	25-34	35-44	45-54	55-64	65-74	75+
2010	-	11	26	104	345	805	1,454
2011	3	7	31	117	344	792	1,538
2012	1	7	33	99	385	791	1,558
2013	-	5	22	107	340	761	1,451
2014*	1	15	30	93	318	813	1,515
Total	5	45	142	520	1,732	3,962	7,516

The 662 individuals (aged 35-54 years) who died from MM in 2010 through 2014 were first exposed to asbestos well into the 1980's and years after that. Among the decedents age 25-34 years who died in 2014, and assuming a 20 year latency period, their first exposure to asbestos occurred in 1994. Their first exposure to asbestos would have occurred when they ranged in age from 5-14 years.

We disagree with EPA's decision to exclude all cancer and non-cancer endpoints that are associated with asbestos exposure, except for MM and lung cancer. The 2016 amendments to TSCA direct EPA to be comprehensive in its assessment of risk. There is no rationale for excluding adverse health endpoints that are attributed to exposure to asbestos.

Exposure to the legacy uses of asbestos continues. It occurs during building remodels, renovations, and demolitions, as noted above. It occurs when homes and buildings are destroyed by extreme weather events, and when water and sewer mains rupture.[17] It occurs when emergency responders serve their communities during fires and after disasters.[18] As long as legacy uses of asbestos are not addressed by EPA, Americans will experience an unreasonable risk of injury to health.

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[16] Death certificate data from the National Center for Health Statistics, National Vital Statistics System. Reported in "Work-Related Lung Disease Surveillance System," U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Respiratory Health Division (Report No. 2017-896).

[17] M. Haag and M. Gomez. Asbestos confirmed in steam pipe that exploded in Manhattan. *New York Times*, July 19, 2018.

[18] Daniels RD, Kubale TL, Yin JH, et al. Mortality and cancer incidence in a pooled cohort of US firefighters from San Francisco, Chicago and Philadelphia (1950–2009). Occup Environ Med. 2014 Jun;71(6):388-97.

Health Risks Associated with Libby Amphibole

APHA disagrees with EPA's decision to exclude from its problem formulation the Libby Amphibole asbestos. The objections we describe above with respect to EPA's decision to exclude legacy uses of asbestos pertain to the Libby Amphibole as well. EPA also fails to make any estimate of the number of existing buildings and products that contain Libby Amphibole and of the number of individuals potentially exposed to it.

Vermiculite from Libby, Montana contains asbestos minerals, including tremolite, winchite and richterite. It was mined and processed into a variety of applications including attic and wall insulation used in homes and cement and building products. An estimated 50 million homes in the U.S. contain vermiculite insulation that is contaminated with Libby Amphibole.[19]

Individuals exposed to Libby Amphibole, both occupational and non-occupationally, experience several well-documented adverse health effects. They include malignant mesothelioma, lung cancer, pleuroparenchymal lung disease, pleural scarring and compromised pulmonary function (See Appendix A).

EPA's investigation of the health and environmental disaster in Libby, Montana identified 245 facilities across the U.S. that received vermiculite from the W.R. Grace mine. EPA estimates that more than 6.1 million tons of vermiculite was shipped to these facilities from 1964 to 1995. ATSDR conducted investigations at 28 of the 245 sites to determine past, current and future pathways of exposure to Libby Amphibole.

Based on the investigations, ATSDR concluded Libby Amphibole may be present in both indoor settled dust and exterior soil at about 100 of the former exfoliation plants (some of which are still used for industrial purposes.)[20] We are not aware of any assessments by EPA, ATSDR, or another federal agency to estimate the number of homes or other buildings that contain Libby Amphibole, particularly in the form of attic and wall insulation.

Libby Amphibole presents an unreasonable risk of injury, in particular to adults and children living in homes with vermiculite insulation. EPA should include Libby Amphibole in its risk evaluation for asbestos.

Exposure Sources and Pathways

EPA's problem formulation and risk evaluation for asbestos should address the aggregate risks of exposure by multiple pathways. It should incorporate the risk from background levels of asbestos in the ambient environment along with concurrent asbestos exposure in homes, workplaces and schools. This is especially relevant given TSCA's requirement for EPA to protect "potentially susceptible or exposed subpopulations," which would include individuals who are exposed to asbestos in more than one environment.

[19] Andrew Schneider and David McCumber. An Air That Still Kills. G.P. Putnam's Sons, 2016.
[20] ATSDR. Summary Report: Exposure to Asbestos-Containing Vermiculite from Libby, Montana at 28 Processing Sites in the United States. October 2008.

We disagree with EPA's decision to exclude from its problem formulation the health risks from the release of asbestos to air, water and waste. By doing so, the agency is evading an assessment of the risks associated with (1) disposal of asbestos-containing debris in landfills and (2) air emissions of asbestos during construction or renovation operations.

We also disagree with EPA's decision to not consider environmental exposure pathways that could be addressed under other laws. This approach would remove all environmental exposure pathways – a significant contributor to human health risk for many chemicals -- from the TSCA risk evaluation process. This dramatic narrowing of TSCA's scope will defeat the central purpose of TSCA reform: (1) to conduct comprehensive risk evaluations on ubiquitous chemicals; and (2) to examine the impacts of these chemicals on health and the environment through all of the diverse pathways and modes of release that may result in harm.

For asbestos, the environmental release exclusion will mean that EPA will not evaluate the risks of disposing of asbestos-containing construction debris and other waste. The data presented in the Problem Formulation document (i.e., Tables 2-4, 2-5, and 2-6) show a dramatic increase in the amount of asbestos going to landfills. Failing to include this disposal information in its risk evaluation means that asbestos fibers released to the air from friable asbestos during building maintenance, repair, renovation or demolition would not be addressed. Air releases and disposals are relevant exposure pathways and a potential risk for the general population and specific subpopulations living near building sites or landfills.

We also urge EPA to include in its risk evaluation the many asbestos-containing products that have not been banned. These include: adhesives, sealants, and roof and non-roof coatings; arc chutes; beater-add gaskets; extruded sealant tape and other tape; filler for acetylene cylinders; high-grade electrical paper; millboard; missile liner; pipeline wrap; reinforced plastics; roofing felt; separators in fuel cells and batteries; vinyl-asbestos floor tile; and any other building material (other than cement). Because EPA has not banned these uses of asbestos, the risk of exposure to from them continues to exist.[21]

Application of Systematic Review in TSCA Risk Evaluations

In a separate letter, we provide comments to EPA on its "Application of Systematic Review in TSCA Risk Evaluations." We want to reiterate that the guidance document is not consistent with best practices for systematic review, including those recommended by the Institute of Medicine.[22] The guidelines outlined in the document should not be applied to any TSCA risk evaluation. EPA should seek peer review from the National Academy of Sciences which has recently convened several expert panels on the subject of systematic reviews.

Occupational Exposure Data

Page 66 of the Problem Formulation of the Risk Evaluation for Asbestos refers to exposure data obtained from the Occupational Safety and Health Administration. EPA states:

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[21] EPA. Significant New Use Rule for Asbestos (83 Federal Register 26922 (June 11, 2018)).
[22] Institute of Medicine. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: National Academies Press, 2011.

"A preliminary summary of OSHA's monitoring data from 2011 to 2016 is presented in Table_Apx B-1. These data represent actual exposure levels of asbestos at specific workplaces encompassing several industry sectors and conditions of use."

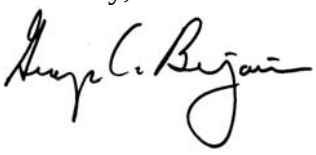
The data in Table_Apx B-1, however, is simply a list of North American Industrial Classification System (NAICS) numbers and NAICS descriptions.

As of August 8, 2018, a corrected version of Table_Apx B-1 was not available from EPA. We would have reviewed and provided comments on the data had it been available.

In conclusion, the 2016 amendments to TSCA provide the best opportunity in decades to address the significant cancer and non-cancer risk for individuals exposed to asbestos. Thirty years ago, EPA's comprehensive risk analysis on asbestos established the foundation for the regulation that would have phased-out nearly all use of asbestos. Today, the evidence of adverse health effects from exposure to asbestos is even more robust. There is no safe level of exposure. Asbestos presents an unreasonable risk of injury and all use should be banned permanently. We strongly urge EPA to reconsider and revise this proposal to ensure it adequately protects the public from the serious health risks associated with asbestos exposure.

Thank you for taking our comments into consideration. Please feel free to contact me with any questions regarding our views on EPA's proposal.

Sincerely,



Georges C. Benjamin, MD
Executive Director

Appendix A: Sample of peer-reviewed papers on the adverse health effects from exposure to Libby Amphibole. (The following papers have been submitted to the EPA docket: EPA-HQ-OPPT-2016-0736-0130)

Alexander BH, Raleigh KK, Johnson J, et al. Radiographic evidence of non-occupational asbestos exposure from processing Libby vermiculite in Minneapolis, Minnesota. *Environ Health Perspect.* 2012;120:44–49.

Al-Ghimlas F, Hoffstein V. Pleuroparenchymal lung disease secondary to non-occupational exposure to vermiculite. *Can Respir J*. 2007;14:164–166.

Antao VC, Larson TC, Horton DK. Libby vermiculite exposure and risk of developing asbestos-related lung and pleural diseases. *Curr Opin Pulm Med*. 2012;18:161–167.

Black B, Szeinuk J, Whitehouse AC, et al. Rapid progression of pleural disease due to exposure to Libby amphibole: "Not your grandfather's asbestos-related disease." *Am J Ind Med*. 2014; 57:1197–1206.

Christensen KY, Bateson TF, Kopylev L. Low levels of exposure to Libby amphibole asbestos and localized pleural thickening. *J Occup Environ Med*. 2013;55:1350–1355.

Dunning KK, Adjei S, Levin L, et al. Mesothelioma associated with commercial use of vermiculite containing Libby amphibole. J Occup Environ Med. 2012 Nov;54(11):1359-63.
Hilbert TJ, Franzblau A, Dunning KK, et al. Asbestos-related radiographic findings among household contacts of workers exposed to Libby vermiculite. *J Occup Environ Med*. 2013; 55:1300–1304.

Larson TC, Lewin M, Gottschall EB, et al. Associations between radiographic findings and spirometry in a community exposed to Libby amphibole. *Occup Environ Med*. 2012;69:361–366.

Rohs AM, Lockey JE, Dunning KK, et al. Low-level fiber-induced radiographic changes caused by Libby vermiculite. *Am J Respir Crit Care Med*. 2008;177:630–637.

Ryan PH, LeMasters GK, Burkle J, et al. Childhood exposure to Libby amphibole during outdoor activities. *J Expo Sci Environ Epidemiol*. 2015;25:4–11.

Sullivan PA. Vermiculite, respiratory disease, and asbestos exposure in Libby, Montana: Update of a cohort mortality study. *Environ Health Perspect*. 2007;115:579–585.

Szeinuk J, Noonan CW, Henschke CI, et al. Pulmonary abnormalities as a result of exposure to Libby amphibole during childhood and adolescence-The Pre-Adult Latency Study (PALS). *Am J Ind Med*. 2017 Jan;60(1):20-34.

Vinikoor LC, Larson TC, Bateson TF, et al. Exposure to asbestos-containing vermiculite ore and respiratory symptoms among individuals who were children while the mine was active in Libby, Montana. *Environ Health Perspect*. 2010;116:1033–1028.

Whitehouse AC. Asbestos-related pleural disease due to tremolite associated with progressive loss of lung function: Serial observations in 123 miners, family members, and residents of Libby, Montana. *Am J Ind Med*. 2004;46:219–225.

Whitehouse AC, Black CB, Heppe MS, et al. Environmental exposure to Libby asbestos and mesotheliomas. Am J Ind Med. 2008;51:877–880.

Winters CA, Hill WG, Rowse K, et al. Descriptive analysis of the respiratory health status of persons exposed to Libby amphibole asbestos. *BMJ Open*. 2012 Nov 21;2(6). pii: e001552