



January 27, 2012

Mr. Kenneth Moss
Chemical Control Division (7405M)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

SUBMITTED TO DOCKET AND BY EMAIL TO MOSS.KENNETH@EPA.GOV

Re: Proposed Significant New Use Rules on Certain Chemical Substances
(EPA-HQ-OPPT-2010-1075)

Dear Mr. Moss:

The American Chemistry Council's Nanotechnology Panel appreciates the opportunity to submit comments on EPA's proposed significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the chemical substances rutile, tin zinc, calcium-doped (CAS No. 389623-01-2) and rutile, tin zinc, sodium-doped (CAS No. 389623-07-8) published in the December 28, 2011 edition of the *Federal Register*.

In the proposed SNURs, the EPA clarified that it considers nanomaterials to include "substances with a particle size less than 100 nanometers, where d10 particle size presents the particle size, as determined by laser light scattering, at which 10 percent by weight of the substance measured is smaller." The Panel strongly supports the 10 percent weight-based threshold as a reasonable criterion for determining whether an intentionally manufactured, insoluble particulate material should be considered to contain a nanomaterial. The Panel's rationale for supporting this approach is explained in the following paragraphs.

Need for a Threshold. Any sample of a solid particulate material will contain a distribution of particle sizes, and that distribution may include particles in the 1-100 nm range. Thus, it is important to set a content threshold for reporting. The 10 percent threshold will effectively capture materials of the size range that have been the subject of nanotechnology discussions in various venues, while also providing increased clarity for manufacturers and users on what materials are affected. Without such a threshold,

Members of the ACC Nanotechnology Panel are Arch Chemicals, Inc., Arkema Inc., BASF Corporation, Bayer MaterialScience, Cabot Corporation, Cytec Industries, The Dow Chemical Company, DuPont, Evonik Degussa Corporation, Ferro Corporation, Procter & Gamble, and 3M.

The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$720 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.



virtually all particulate matter could be considered to contain a nanomaterial, as there is likely to be some small fraction of particles in the nanoscale range.

Reasonableness of a 10 Percent Threshold. Any threshold chosen must be adequately protective of health and the environment, while at the same time recognizing the practical limitations associated with analytical methods available for quantifying materials at or below the threshold. Based on currently available information on health and environmental effects of nanomaterials and detection limits for generally available analytical methods, the Panel believes that the 10 percent weight threshold strikes a reasonably conservative balance between these competing concerns.

Appropriateness of a Weight-Based Threshold. The Panel strongly supports the weight-based threshold as opposed to a threshold based on particle number or surface area. While a threshold based on particle number or surface area may theoretically be more appropriate in certain instances (e.g., when significant exposure to an aerosolized material is likely), particulate products are generally not intentionally aerosolized. In cases where aerosolization may occur, industrial hygiene measures appropriate for controlling exposures to particles larger than 100 nm have been shown to be generally effective for particulates smaller than 100 nm as well.¹ In addition, methods and instrumentation for performing weight-based particle size measurements (e.g., cascade impactor or dynamic light scattering) are more widely available than techniques for performing measurements based on particle number (e.g., electron microscopy) or surface area. Methods for particle number and surface area can be less accurate and more technically difficult to perform and interpret, or are not applicable to all materials.

Additional Elements of a Nanomaterial Definition. In addition to the 10 percent weight threshold, the Panel believes there are other important elements that should be included in any definition of a nanomaterial. These include recognizing that aggregates and agglomerates are not the same as the primary particles of which they are comprised and that many agglomerates may not disagglomerate readily in any medium. How aggregates and agglomerates get included in the category “nanomaterial” is important. The Panel is preparing a manuscript for publication that further discusses these elements and provides real-world examples of their application.

Please do not hesitate to contact me if you have any questions about these comments.

Sincerely,



Jay West
Senior Director
Chemical Products and Technology Division
ACC Nanotechnology Panel

¹ See: Rengasamy, S., and Eimer, B.C. 2012. Nanoparticle filtration performance of NIOSH-certified particulate air-purifying filtering facepiece respirators: evaluation by light scattering photometric and particle number-based test methods. *J Occup Environ Hyg.* 9(2):99-109; Rengasamy, S., and Eimer B.C. 2011. Total inward leakage of nanoparticles through filtering facepiece respirators. *Ann Occup Hyg.* 55(3):253-63; Rengasamy, S., Miller, A., and Eimer, B.C. 2011. Evaluation of the filtration performance of NIOSH-approved N95 filtering facepiece respirators by photometric and number-based test methods. *J Occup Environ Hyg.* 8(1):23-30; Rengasamy, S., Eimer, B., and Shaffer, R.E. 2010. Simple respiratory protection—evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000 nm size particles. *Ann Occup Hyg.* 54(7):789-98.