

14 October 2017

The Nanotechnology Panel of the American Chemistry Council (the Panel)¹ has prepared these preliminary Comments on the Massachusetts Chemical & Materials Fact Sheet: Engineered Nanomaterials (August 2017).² The purpose of the Toxic Use Reduction Institute's (TURI) fact sheets is to "describe the hazards, exposure routes, uses and alternatives, and regulatory context for selected chemicals."³ The Panel is concerned that the fact sheet gives the erroneous impression that putting "nano" in front of a substance's name automatically makes it inherently dangerous. It conveys an uneven message through its use of inaccurate or incomplete information. Nanomaterials have been in widespread use for decades, but the fact sheet gives the impression that nanomaterials are largely new and that little is known about them. That is inaccurate. The comments below are organized using the headings in the TURI fact sheet.

Engineered Nanomaterials: What are They?

1. Paragraph 2, last sentence: The citation for this section (#2) clearly states that nanomaterials can *in theory* be engineered from nearly any chemical substance or mineral. The number of nanomaterials in commerce is actually rather limited.
2. Paragraph 3, second sentence: The sentence would be more accurate if it said "may exceed" rather than "often far exceed." The properties that do and do not change depend on the material, the manufacturing process, and other factors.
3. Paragraph 4, first sentence: This sentence is unclear. Is it speaking to commercial research and development or public research dollars? It's worth noting that the cumulative federal investment in environmental, health, and safety research was more than \$1 billion for the years 2006-2015.⁴ Furthermore, materials like carbon black and titanium dioxide have been around for a long time. This sentence is therefore not accurate.

Human Health and Environmental Concerns

1. Paragraph 1, first sentence: The sentence would be more accurate if it said "properties that may make."
2. Paragraph 2, second sentence: The sentence would be more accurate if it said "a widely recognized route of *potential* human exposure." Although the importance of personal protective equipment (PPE) and exposure control measures are noted elsewhere, this sentence gives the impression that all persons working with nanomaterials are being exposed.
3. Paragraph 2, second sentence: The second half of the sentence is not reflective of the cited source (EPA's 2007 "Nanotechnology White Paper"). The white paper's sections on environmental fate go into considerable detail about various processes that can cause nanomaterials to absorb to other particles in the environment and effectively settle out.
4. Paragraph 3, first sentence: The fact sheet does not acknowledge that the vast majority of nanomaterials exist not as discrete, individual particles, but as aggregates and agglomerates, the size of which can be much larger than the nanoscale.

¹ Members of the ACC Nanotechnology Panel are 3M, BASF Corporation, Cabot Corporation, Chemours, DuPont, Evonik Corporation, and Procter & Gamble.

² <https://www.turi.org/content/download/11060/180362/file/Fact%20Sheet.%20Nanomaterials.%20August%202017.pdf>

³ https://www.turi.org/TURI_Publications/TURI_Chemical_Fact_Sheets

⁴ <https://www.nano.gov/you/environmental-health-safety>.

5. Bullet 2: This is an extreme example that is not characteristic. A 100nm spherical particle has only 10 times more mass specific surface area than a 1 micron particle. Individually a single nanoparticle has far less surface area than a micron-scale particle.
6. Bullet 4: The ability to deliver complex materials attached to surface is actually a desirable property for medicinal uses of nanomaterials.
7. Paragraph 4: The fact sheet does not acknowledge that there are nonhazardous nanomaterials. Also, reference 5 states, "There is no evidence that particles below 100 nm, the threshold definition of a NP, show any step-change in their hazard meaning that there is no evidence of novel 'nano-specific hazard'."

Examples of Nanomaterials: Carbon nanotubes

Health Effects

1. Overall: It is not clear that the pulmonary outcomes from experiments on carbon nanotubes (CNTs) would be different than those anticipated from WHO fibers (i.e., inorganic fiber dusts, except asbestos fibers, with a length >5 microns, a diameter <3 microns and a length-to-diameter ratio of >3:1)? The impression conveyed by the fact sheet here is that "nano" is uniquely dangerous.
2. The fact sheet does not accurately qualify that questions about inhalation exposure are in the occupational realm. For consumers, a NIOSH study evaluating the lifecycles of CNTs has found decreased toxicity as CNTs are incorporated into polymers for example. The study concludes "Our study provides perspective that, while the number of workers and consumers increases along the life cycle, toxicity and/or potential for exposure to the as-produced material may greatly diminish".⁵
3. Pulmonary effects should be put into a real world context, not just the artificial context of laboratory animals first exposed to a cancer initiating substance prior to CNT exposure. A 2013 NIOSH study concludes: "These findings showed a limited pulmonary inflammatory potential of MWCNT at levels corresponding to the average inhalable elemental carbon concentrations observed in U.S.-based CNT facilities and estimates suggest considerable years of exposure are necessary for significant pathology to occur at that level."⁶

Quantum Dots

Health Effects

1. The fact sheet does not mention a 2012 study published in the May issue of Nature Nanotechnology (Ye, et al) that reported on an evaluation of adverse responses to intravenous quantum dots in non-human primates. No adverse responses were observed over the 90 day observation period. The study did note that long-term effects need to be evaluated.⁷
2. The TURI fact sheet seems to choose to rely on cadmium toxicity, not actual data from the evaluation of quantum dots themselves.

Nano Titanium Dioxide

⁵ Bishop L, Cena L, Orandle M, et al. (2017) In Vivo Toxicity Assessment of Occupational Components of the Carbon Nanotube Life Cycle To Provide Context to Potential Health Effects. ACS Nano 11(9):8849-8863 doi:10.1021/acsnano.7b03038

⁶ Erdely A, Dahm M, Chen BT, et al. (2013) Carbon nanotube dosimetry: from workplace exposure assessment to inhalation toxicology. Particle and fibre toxicology 10(1):53 doi:10.1186/1743-8977-10-53

⁷ Ye L., Yong K., Liu L., et. al. (2012) A pilot study in non-human primates shows no adverse response to intravenous injection of quantum dots. Nature Nanotechnology 7: 453-458 doi:10.1038/nnano.2012.74

1. The pulmonary inflammation observations have only been seen in rats at very high doses under the conditions of lung overload. Under such conditions, one would predict that a poorly soluble material of low toxicity would likely generate a similar result. Nano titanium dioxide is not unique.
2. It is generally understood that nano titanium dioxide does not possess specific genotoxicity and any tumor formation is a result of the prolonged, chronic inflammation induced in animal studies under conditions of lung overload.⁸ The Panel believes the applicability of such prolonged, artificial conditions to humans is questionable.

Nanosilver

1. Please see the extensive comments submitted by Dr. Rosalind Volpe of the Silver Nanotechnology Working Group (sent October 3, 2017, to Michael Ellenbecker, TURI, and Molly Jacobs, Lowell Center for Sustainable Production).

Safer Alternatives

1. First paragraph, second sentence: We agree that commercialization of products should not proceed until hazards are well understood. That is true of any product, not just nanomaterials. Singling out nanomaterials shows a misunderstanding of the history and facts surrounding the technology, as is true elsewhere in the fact sheet.
2. Second paragraph, second sentence. We question the statement “For numerous functions in a given application, such as material strength or optical properties, existing bulk materials may satisfactorily achieve the desired function and should be used instead of nanomaterials.” If that is the case, why would companies invest the time and energy into milling/grinding the non-nanoscale form into a nanoscale form? That investment would only make sense if the nanoscale form had a property that was desirable relative to the non-nanoscale form.

Considerations for the Safer Development and Safer Use of Engineered Nanomaterials

1. Fourth paragraph. As with much of the content in the latter part of the fact sheet, the section on having plans and controls that protect workers, consumers, communities, and the environment is true for any substance, not just nanomaterials. The fact sheet seems to continuously give the impression that nanomaterials are especially dangerous.

Regulatory Context

1. Second paragraph. The fact sheet does not mention that the Toxic Substances Control Act (TSCA) “requires that EPA be immediately notified when substances or mixtures present a substantial risk of injury to health or the environment.”⁹ That requirement applies equally to nano-scale and non-nano forms of substances.

⁸ Chen, T., Yan, J. and Li, Y. (2014). Genotoxicity of titanium dioxide nanoparticles. *Journal of Food and Drug Analysis* 22(1):95-104 doi.org/10.1016/j.jfda.2014.01.008; See also discussion throughout European Chemicals Agency Committee for Risk Assessment (RAC). (2017). Opinion: proposing harmonised classification and labelling at EU level of Titanium dioxide. Adopted September 14, 2017.

⁹ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/reporting-tsca-chemical-substantial-risk-notice>