Perception, Assessment, and Management of the Potential Risks of Nanotechnology: A Consumer Perspective

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Consumer Reports (CR) on nanotechnology

- July 2007 CR article “Nanotechnology: Untold promise, unknown risks”
- Tested 8 sunscreens with TiO$_2$ and ZnO; all were nano, only 1 labeled as nano—Keys Solar RX
Tested 5 sunscreens containing TiO2 and ZnO which were claimed as not containing nanoparticles, yet our tests showed nanoparticles were present.
Improvements in nano

• NNI funding more risk assessment research, so have more studies on hazards of certain ENMs
• More labs testing using standardized commercially available NPs. However, these usually are not the ENMs that are actually being used in consumer products. NNI needs to do a better job to get detection methodology relevant to consumer products actually on the market, particularly those products used on or in the body
• NNI website (nano.gov) is not user friendly; very hard to find the research on hazards and risk assessment. The brochures overhype the potential benefits of ENMs.
• Good work being done on nano RA at CPSC, but that is also hard to find
Improvements in nano

• ILSI NanoRelease Consumer Products
  – Very broad participation on steering committee
  – Will focus testing on 2 CNT-composites: CNT-epoxy and CNT-rubber
• ILSI NanoRelease Food Additives
  – specific NPs haven’t yet been chosen
  – Work is crucial since very few studies on NP and uptake and interactions in the gut
Improvements needed: FDA

• 2006  Consumer groups, led by International Center for Technology Assessment, petition FDA to require oversight of engineered nanomaterials in FDA regulated products, especially those put on or in body; specific action requested on sunscreens with nano-TiO$_2$
• 2007 FDA workshop on Nanotechnology
• 2008  September FDA Nanotechnology Public Meeting
• 2011 December  Consumer groups sue FDA for lack of action on 2006 petition
Improvements needed: FDA

• 2012 April FDA releases 2 Draft Guidance for Industry:
• “Assessing the Effects of Significant Manufacturing Process Changes, including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives”
  – ENMs “likely would not be covered by existing GRAS” and that industry would have to submit product data with ENMs for a “formal pre-market review.”

• Safety of Nanomaterials in Cosmetic Products
  – FDA suggests industry may need to revise safety testing due to unique properties of ENMs and suggests tiered testing approach
  – FDA lacks statutory authority to require premarket testing of cosmetics
Improvements needed: FDA

- Draft Guidance for Industry: voluntary not mandatory
- Agency assumes the existing battery of tests are “probably adequate” for testing safety of ENMs

- 2011 Safe Cosmetics Act introduced in Congress, would require testing and labeling of ENMs in cosmetics
Improvements needed: EPA

• 2005 Office of Pollution Prevention and Toxics (OPPT) begins discussion of National Materials Stewardship Program (NMSP), voluntary program for manufacturers of ENMs, as part of TSCA
• 2008 January NMSP launched
• 2009 Interim report: “approximately 90% of the different nanoscale materials that are likely to be commercially available were not reported under the Basic Program” and “The low rate of engagement [only 4 companies] in the In-Depth program suggests most companies are not inclined to voluntarily rest their nanoscale materials”
Improvements needed: EPA

- NMSP a failure
- 2011 May  EPA finalizes a significant new use rule (SNUR) for multi-walled CNTs
- 2013 February EPA proposes SNURs for 37 chemicals, including 14 nanomaterials, particularly CNTs v 5(e) consent orders under TSCA requiring protective measures to limit workers' exposures or otherwise mitigate potentially unreasonable risk.
- TSCA chemical notification requirements—low-volume exemption for chemicals produced in volumes of 10,000 kilograms or less per year, and “low release/low exposure” exemption. These exemptions need to be revoked or drastically lowered for ENMs
Improvements needed: EPA

• 2008 May A range of NGOs, led by ICTA (and including CU), petition EPA to classify nano-silver as a new pesticide and require separate testing for nano-silver under FIFRA.

• 2011 June EPA proposes regulating pesticides that use nanotechnology in a Federal Register notice

• EPA’s proposed regulation of nanopesticides is held up at OMB

• EPA has begun product-by-product data call-in notices for nano-silver products under FIFRA section 3(c)(2)(B)