Nanomaterials and TSCA

American Chemical Society Briefing

Nanomaterial Safety: Do We Have the Right Tools?

June 27, 2012

Richard A. Denison, Ph.D.

Senior Scientist

EDF ENVIRONMENTAL DEFENSE FUND™

Finding the ways that work

Topics

TSCA

- Nano oversight under current TSCA: Gaps and challenges
- Changes under proposed reform legislation

EPA efforts

- Data call-in, new use notification, test rule
- Industry resistance and OMB delays

Legislative authorities

- Toxic Substances Control Act of 1976 (TSCA)
  - Covers most uses of nanomaterials in industry and commercial/consumer products
- Reform legislation
  - Safe Chemicals Act of 2011 (S. 847) introduced by Sen. Lautenberg

1. Are nanomaterials "new" or "existing" chemicals?

TSCA

- In 2007, EPA ruled it can't consider more than chemical structure to decide whether a chemical is "new" or "existing" under current TSCA.
  - Decision eliminated only authority for pre-manufacture review for new nano forms of existing chemical structures.
  - EPA does consider fullerenes, carbon nanotubes, etc., that have no conventional counterpart to be "new."
- In 2009, new EPA leadership revisited this decision
  - Tried to develop a proposal to identify new nano forms of existing chemicals to be "significant new uses"
    - would be subject to EPA notification/review (SNUR)
  - Cannot reach nanomaterials already in use

1. Are nanomaterials "new" or "existing" chemicals?

Reform legislation

- Authorizes EPA to identify “a variant of a chemical substance to be a new chemical substance”
- Defines “variant” by reference to “special substance characteristics:” “physical, chemical, or biological characteristics … that may significantly affect the risks posed by substances exhibiting those characteristics … considering:
  - size or size distribution;
  - shape and surface structure;
  - reactivity;
  - any other properties that may significantly affect the risks posed.”
- Alternatively allows EPA to identify a variant as a “new use”

2. Will “new” NMs get proper review?

TSCA

- New chemical notifier need not identify as NM.
- Notification exemptions "swallow" many NMs:
  - Low volume exemption (LVE): ≤10,000 kg/yr
  - Low release/low exposure exemption (LOREX): EPA uses mass-based criteria or exposure control efficacy measures.
  - The exemption for certain polymers based on presumed low bioavailability.

2. Will “new” NMs get proper review?

Reform legislation

- New chemical and new use notifiers must include data on substance characteristics.
- Notification exemptions not automatically carried over from TSCA.

3. Can NMs be tracked once in commerce?

TSCA: Chemical data reporting (CDR, formerly IUR) is only mechanism:

- Only producers/importers, not downstream users.
- Threshold is 25,000 lb/yr/site – will capture only CNTs, certain ceramic NMs.
- Exemptions: polymers, R&D, imported in product, small manufacturer.
- Not required to flag reported substances as NMs.
- Wide latitude to claim CBI – NM, submitter identity

3. Can NMs be tracked once in commerce?

Reform legislation

- Manufacturers must update information:
  - at a minimum every 3 years
  - whenever significant changes occur or new information is developed or obtained
- Annual production volume must be reported; no threshold.
- EPA has authority to require reporting by downstream users.
- Exemptions: R&D
- Not specifically required to flag NMs, but reporting of special substance characteristics required.
- Narrowing of CBI claims

4. Submission of already existing information

TSCA

- EPA can require one-time reporting case-by-case.
  - EPA's proposed rule stuck at OMB
- Limited to pre-existing information
- Small manufacturers exempt (though definition can be altered).
  - EPA proposed rule includes lower threshold
- Requires full notice-and-comment rulemaking.

Reform legislation

- Automatic submission and updating required.

5. Development of new data

TSCA

- To require testing, EPA must find substance:
  - may present an unreasonable risk OR
  - is produced in substantial quantities <u>and</u> results in substantial release/exposure.
- EPA rarely makes 1st finding, but 2nd finding requires:
  - substantial production = 1 million lbs/yr, and
  - substantial release = 1 million lbs/yr or 10% prod'n.
- EPA must also find that:
  - existing data inadequate for risk assessment; and
  - testing is needed to develop the data.
- EPA has nano test rule in development (not yet to OMB)

5. Development of new data

Reform legislation

- Minimum data set required up front.
- EPA retains authority to require additional testing as needed to perform duties.
  - may include testing for special substance characteristics

EPA's efforts under current TSCA

- EPA has tried to propose reporting, significant new use notification and test rule
  - All are information-gathering mechanisms – none would regulate production or use of even a single nanomaterial
- Yet industry is claiming over-regulation
  - Industry sounded alarm over "an over-stimulated, political regulatory process"
  - NanoBusiness Alliance 1/7/11 letter to Rep. Issa
  - Multiple meetings with OIRA/OMB to raise concerns
- Proposed rules stuck at OIRA/OMB:
  - 583 days and counting
  - Won't even allow release for public comment
  - Concern that any regulation will stifle innovation
  - ACC companies refuse to support release

Why the hold-up?

- OSTP/OMB "*Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials*"
  - Issued June 9, 2011
  - Signed by:
    - John Holdren, Director of OSTP
    - Cass Sunstein, Administrator of OIRA
    - Islam Siddiqui, Chief Agriculture Negotiator, USTR
  - Principles not surprising or significant departure
    - Seek and develop adequate information
    - Base decisions on science, consider costs and benefits
    - Controls proportionate with level of risk identified

For more information

- My series on obstacles to regulating nano under TSCA:
  - 5 parts, start here: http://bit.ly/nnoDeg
- EPA nano policy/regulation pages:
  - http://www.epa.gov/opptintr/nano/
- EDF Chemicals and Nanomaterials blog:
  - www.edf.org/chemandnano