

# Nanotechnology regulation in Washington and Brussels: TSCA vs. REACH

DTSC Nanotechnology III Symposium

Nano Regulation - Anticipating the Smallest  
Threats and the Largest Opportunities

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finding the ways that work

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

## TSCA

- EPA says it can't consider more than chemical structure to decide whether a chemical is "new" or "existing".
- Decision eliminates only authority for pre-manufacture review for new nano forms.
- EPA does consider buckyballs, carbon nanotubes, etc. that have no bulk counterpart to be "new."

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

## REACH

- EU also considers nano forms of bulk substances to be “existing” chemicals. BUT:
- REACH practically eliminates new/existing distinction.
- Both types of chemicals be registered, tested, their uses identified and assessed.
- Introduction of new nano forms requires updating of registrations.

## 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):  $\leq 10,000$  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?

### REACH

- All new NMs  $\geq 1$  tonne/yr must be registered.
- All nano forms of existing substances must be included in their registrations.
- Novel properties/uses must be specifically accounted for.
- Polymers are exempt from REACH.

### 3. How many bites at the apple for "new" NMs?

TSCA: EPA typically gets only one bite.

- Once reviewed and production starts, notification by others is either:
  - not required at all, or
  - if EPA also issues a SNUR\*, required only if conditions of SNUR are exceeded.
- Future changes in production or use pattern do not trigger new review.

\* SNUR = Significant New Use Rule

### 3. How many bites at the apple for "new" NMs?

#### REACH

- All producers must register.
- Increasing data as volume increases.
- Prompt updating required based on changes in use or risk information.  
(“perpetual” SNUR or SNAc)

## 4. New chemical review: Time and data limitations

### TSCA

- 90 days (extension/suspension possible).
- No up-front minimum data required.
- Predictive models don't work well for NMs.
- Case-by-case, EPA can require testing if it finds risk or high exposure potential.
- Lack of data not enough to require testing.

## 4. New chemical review: Time and data limitations

### REACH

- Minimum dataset required, based primarily on volume.
- May not be sufficient for low-volume NMs.
- Case-by-case, ECHA can require additional testing.

## 5. Can existing NMs be tracked once in commerce?

### TSCA

- Inventory Update Rule is only mechanism:
  - Infrequent: every 5 years, one year's production.
  - 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.
  - No requirement to flag reported substances as NMs.

## 5. Can existing NMs be tracked once in commerce?

### REACH

- Updating of registrations/assessments req'd:
  - when new volume threshold reached or
  - when new uses or data emerge.
- REACH extends to downstream users.
- Some exemptions: polymers, R&D.
- Lesser requirements for NMs in products where such use is not already registered.

## 6. Submission of already existing information

### TSCA

- EPA can require one-time reporting case-by-case.
- Small manufacturers exempt (though definition can be altered).
- Generally requires full notice-and-comment rulemaking.

### REACH

- Automatic submission and updating of registrations required for all substances.

## 7. Voluntary data submission

### Nanoscale Materials Stewardship Program (NMSP)

- Open-ended, encouraged 6 months, but runs 2+ yrs.
- 29 companies have submitted info on 123 NMs.
  - EPA had projected 180 companies on 240 NMs.
- 63 NMs from 1 company, most only basic identity.
- 13 companies' submissions posted, other 16 all CBI.
  - Much data in posted submissions also CBI.

## 7. Voluntary data submission

- Most data on conventional NMs carbon black, amorphous silica, TiO<sub>2</sub>, not much on other NMs.
- EPA Interim Report (1/09):
  - Submissions relate to <10% of >1,000 NMs likely in commercial production.
  - Very little health and environmental data provided.
  - EPA doesn't know if a company's submissions cover all or only a subset of NMs it produces, or if data on a given NM is complete or selective.
  - Only 4 companies agreed to consider doing testing.
- EPA now reportedly developing mandatory reporting and test rules.

## 8. Development of new data

### TSCA

- To require testing, EPA must find substance:
  - may present an unreasonable risk OR
  - is produced in substantial quantities and results in substantial release/exposure.
- EPA rarely makes 1<sup>st</sup> finding, but 2<sup>nd</sup> 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.

## 8. Development of new data

### REACH

- Minimum dataset required, based on volume.
- May not be sufficient for low-volume NMs.
- Case-by-case, ECHA can require additional testing.

## 9. Regulating “existing” NMs

### TSCA

- EPA must find:
  - substance “*presents or will present* an unreasonable risk,”
  - regulation’s benefits outweigh costs,
  - alternatives are available,
  - proposed control is the least burdensome it could have proposed, and
  - no other statute could address the concern.
- EPA failed even for asbestos, has never tried again.

## 9. Regulating “existing” NMs

### REACH

- Many of the same factors are in play:
  - Evidence of significant risk
  - Benefits versus costs
  - Availability of alternatives
- BUT burden of proof is on industry, not government.

## 10. CBI and public access

- TSCA
  - Health & safety study results can't be claimed CBI, but submitter and chemical identity can be.
  - Up front justifications not usually required.
  - Review, approval of CBI claims not required.
  - EPA must challenge CBI claims case-by-case, lacks resources to do so.
  - No expiration date for CBI claims, nor a requirement to reassert or rejustify them.
  - EPA cannot disclose CBI to foreign, state, local or tribal governments.

## 10. CBI and public access

- REACH:
  - Requires public access to much of submitted information – and to government decisions made based on that information.
  - Delineates information to be: a) kept confidential, b) always made public, and c) made public unless justification provided and deemed warranted by govt.
  - Provides for foreign governments to have access to CBI submitted under REACH.