



LEGAL ASPECTS OF ENGINEERED NANOMATERIALS

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How Are Chemicals Regulated?

- Federal vs state authority to regulate chemical-related activity
 - *Preemption*

- Federal statutes:
 - *Toxic Substances Control Act (TSCA)*
 - *Food, Drug & Cosmetic Act (FDCA)*
 - *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)*
 - *Clean Air Act*
 - *Clean Water Act*
 - *Safe Drinking Water Act*
 - *Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)*
 - *Occupational Safety and Health Act (OSHA)*
 - *Federal Hazardous Substances Act*
 - *Consumer Product Safety Act*

California Agencies That Regulate Chemical Exposures

- DTSC
- ARB
- Water Boards
- DPR
- Cal/OSHA
- CDPH
- CalRecycle
- Other agencies

Molecular Structure vs Properties

- Nanomaterial has the same molecular structure as its larger counterpart (bulk material).
- But nanomaterials have chemical, physical, and biological properties that are different from bulk materials.
- Increased surface area of nanoparticles causes high levels of reactivity, solubility, and conductivity compared with bulk material.
- These altered properties may affect safety and toxicity.

Toxic Substances Control Act

- TSCA enacted in 1976
- First federal law to regulate industrial chemicals
- Administered and enforced by US EPA
- Amended for first time in 2016 (Frank R. Lautenberg Chemical Safety for the 21st Century Act)

Former TSCA	Amended TSCA
Did not expressly preempt state regulation	Expressly preempts state regulation
EPA used cost-benefit analysis	EPA may not consider costs or non-risk factors
EPA need not evaluate risk of new chemicals	EPA must find new chemical is safe

TSCA's "Chemical Substance"

- 15 USC § 2602(2)(a)
- "Chemical substance" means "any organic or inorganic substance of a particular molecular identity"
 - *Based on molecular structure, not properties*
- Sen. Frank Lautenberg (D-NJ) proposed a new "thing" to regulate, a "special substance characteristic":
 - *Would have meant, "a physical, chemical, or biological characteristic, other than molecular identity, that [EPA] determines . . . may significantly affect the risks posed by substances exhibiting that characteristic."*
 - *Would have differentiated material by property, not molecular structure*
 - *Would have given EPA clear authority to regulate nanomaterial*

TSCA Treatment of Nanomaterial

- EPA considers some nanomaterial a “significant new use” (SNU) of a current chemical substance (40 CFR Part 721)
- EPA then issues a rule (regulation) called a “significant new use rule” (SNUR)
- Does not require data reporting, just notice before manufacturing
 - “*significant new use notice*” (SNUN)

TSCA's Nano Reporting Rule

- 40 CFR § 704.20 (effective August 14, 2017)
- CDPH submitted a comment letter during the rule's notice-and-comment period in 2015
- Information-gathering rule requiring manufacturers/processors of nano-scale material to submit info regarding properties of nanomaterial; production volume; use; methods of manufacturing; exposure; release; risk-management practices for workers; environmental and health effects, if known.
- Rule includes element of intent
 - *Reporting only required when "unique and novel" properties of the material are (1) due to its nano-scale and (2) are the reason the substance is manufactured*
 - Example: Someone produces nano-gold *because* it is black and not yellow = "unique and novel property." But someone produces nano-gold to change the thermal conductivity of a dispersion ≠ "unique and novel property" because the change in thermal conductivity would happen with larger particles as well.

TSCA's New "Risk Evaluation"

- 15 USC § 2605
- EPA "shall conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use."
 - *EPA interprets "conditions of use" to mean only future intended uses*
 - Excludes "legacy" use and exposure through intentional or unintentional misuse
- EPA may not consider costs or non-risk factors when determining whether a chemical poses an "unreasonable risk"
- EPA will not consider exposures resulting from uses addressed through other laws
 - *Essentially will result in ignoring cumulative effects of a chemical across the environment*

But...

- States may likely regulate “conditions of use” not considered by EPA in its risk evaluations mandated by the amended TSCA
 - *Chemical manufacturers will likely still face varying regulations throughout the nation*
- States may still regulate new chemicals
 - *700 new chemicals are introduced each year into commerce*
- States can ask EPA for waivers to address local needs
 - *(If EPA misses a deadline, the waiver is granted as a matter of law)*
- State agencies still have other avenues for regulation
- Environmental 501(c)(3)'s are already suing EPA over its interpretations of TSCA

Public Health & State Government

- Public health is traditionally part of a state's police powers
 - *Police powers = protecting the health, safety, and morals of the community*
- State's public health *parens patriae* power
 - *Power to protect the interests of minors and incompetent persons*
- Police powers flow from view of democracy that sees government's essential task as protecting and promoting both private and group interests
 - *The "common good" = welfare of individuals considered as a group*
- For 40 years, federal and state governments regulated industrial chemicals together
 - *State's power seems preempted under amended TSCA*
- Chemical lobby is powerful

Other Actions State Agencies Can Take

- Require disclosure, reporting, and monitoring
- Submit comments during federal rulemaking process
- Educate workers and citizens
- Create public databases
- Require labeling (in California, a hang-tag is not a “label”!)
- Submit hazard-analysis data to EPA and other federal agencies
- Keep abreast of the science and create the policy
- Propose state legislation
- Lobby federally
- Prepare for emergencies resulting from exposure to nanomaterial

Questions?

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