



How Can Standards for Graphene Nanomaterials Support TSCA Compliance?

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TSCA is not an opera . . .



Lautenberg Chemical Safety Act

A More Effective Way to Regulate Chemicals

EXISTING CHEMICALS

EPA will conduct risk-based reviews of chemicals in commerce

Inventory Reset

EPA maintains an inventory of chemicals, but it is difficult to tell which are used today and which are no longer in use

LCSA requires the inventory be updated so EPA can focus on chemicals actually in use today

Prioritization

EPA will screen all chemicals in active use to identify low and high priorities for risk evaluation. Prioritization will be based on factors including hazards, uses and exposures to people and the environment, including vulnerable groups like infants, children, pregnant women and the elderly

Low Priority Chemicals

Chemicals can remain in use but can be reprioritized based on new information

High Priority Chemicals

EPA will conduct a thorough risk evaluation

The first 10 high priorities must be drawn from EPA's existing TSCA Chemical Work Plan list

NEW CHEMICALS

EPA must review and make an affirmative safety determination before a new chemical can come to market

Information Submitted to EPA *

Manufacturers provide information about new chemicals and new chemical uses to EPA

Risk-Based Review

EPA reviews information including chemical characteristics, available testing and exposure data and intended uses

EPA can request more information if needed

Safety Determination

If EPA finds the chemical is not likely to present an unreasonable risk, it proceeds to market

If the chemical presents an unreasonable risk, EPA may apply risk management measures

Risk Evaluation

EPA Risk Evaluations will:

- Be based solely on health and environmental information
- Consider a chemical's conditions of use
- Rely on the best available studies and weight of scientific evidence
- Consider risks to vulnerable groups

LCSA makes it easier for EPA to request more testing and data from producers when needed

20 risk evaluations must be underway within 3.5 years

Safety Determination

EPA will determine if a chemical meets the law's safety standard or requires risk management

Chemical Meets Safety Standard

Chemical may be used for its intended uses

Chemical Needs Risk Management

EPA's options include:

- Labeling Requirements
- Use Restrictions
- Phase Outs
- Bans

About the Lautenberg Chemical Safety Act

After years of negotiation and with input from many stakeholders, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) to reform the regulation of chemicals in commerce. The LCSA, enacted on June 22, 2016, protects health and the environment; supports economic growth; and promotes America's role as the world's leading innovator.

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Notifications for new nanomaterials are not a walk in the park.



Is your Business Ready for the PMN Challenge?

- “Chemical substance” defined as having a particular molecular identity. If not on TSCA Inventory = new
- EPA reviews ~ 1000 new chemical submissions/year
- Statutory 90 day review period is not being met
- Historically ~10% of the assessments resulted in regulation, withdrawal or ban

. . . Regulated or withdrawn - ~80%



- The **safety standard** requires attention on use
- EPA **must issue decision outcomes** before manufacture begins
- EPA **must regulate** based on **insufficient information**

Effects that flow from TSCA regulation of a new chemical

- Same deal for future filings
- Section 12(b) export notification
- Chemical Data Reporting (CDR) threshold drops from 25,000 lbs./yr. to 2,500 lbs./yr.
- Must notify EPA within 30 days of the sale of the business in case of consent order

How can ANSI standards support TSCA compliance for **new** nanomaterials?

- Regulations lag behind innovation – standards are ahead of the tide
- Risk assessment and relevant human and environmental endpoints
 - E.g., **ISO/TR 13121:2011, Nanotechnologies – Nanomaterial risk evaluation**
- How to address key aspects of new chemical form
 - Inhalation exposures (particle size, dust)
 - Exposure and environmental release (solubility, Log Kow, PBT)
 - Wastewater treatment removal efficiency
 - Recommended container clean out and disposal practices
- Work practices and personal protective equipment
 - E.g., **ISO/TR 12885:2008, Nanotechnologies – Health and safety practices in occupational settings relevant to nanotechnologies**
 - E.g. **ISO/TR 13329: 2012, Nanomaterials – Preparation of material safety data sheet (MSDS)**
- Physical-chemical characterization data relevant to graphene
 - E.g., **ISO/TR 13014:2012, Nanotechnologies – Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment**
- Development and validation of test methods



Existing nanomaterials – section 8 reporting

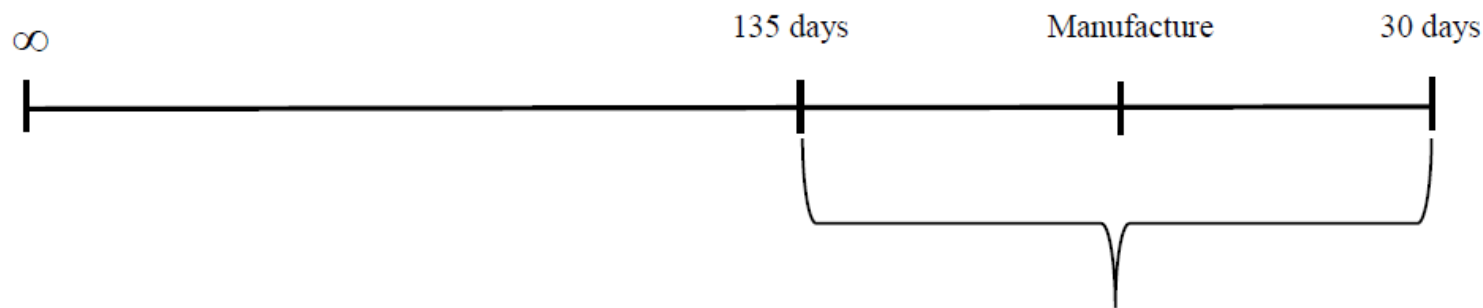
- **Manufacture, import or process a reportable chemical:**
 - Solid at 25 C and atmospheric pressure
 - The primary particles, aggregates, or agglomerates are in the **size range of 1-100 nm** *in at least one dimension* and exhibit **unique and novel** characteristic or properties because of their size
 - **ISO/TR 80004-1:2015, Nanotechnologies – Vocabulary – Part 1: Core terms referenced for definitional development**
- **Required for certain changes for same chemical:**
 - **Different morphology or shape**
 - **If process change** results in the size and property changes described in the rule
 - **Different chemical coating**
 - 82 Fed. Reg. 3641 (Jan. 12, 2017); 82 Fed. Reg. 22088 (May 12, 2017)

When is a nanomaterial report due?

40 C.F.R. §704.20

August 14, 2018 if manufactured or processed anytime during the three years before August 14, 2017.

EPA Imposed on-going reporting for first time under section 8(a) . . . so if manufactured or processed after **August 14, 2017**....



Intent to manufacture/process established at least 135 days prior to manufacturing

Report at least 135 days before manufacturing/processing

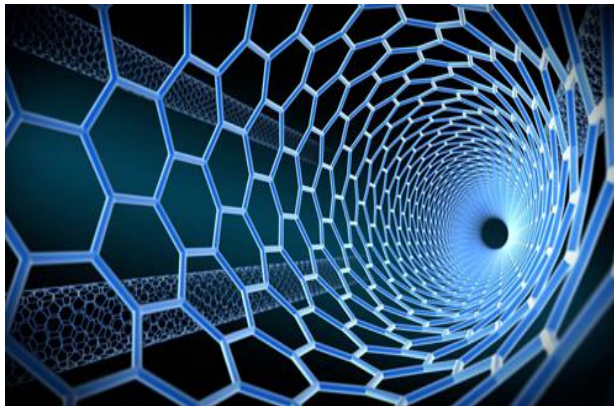
Intent to manufacture/process established fewer than 135 days before manufacture

Report no later than 30 days after forming intent to manufacture/process

Working Guidance:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/working-guidance-epas-section-8a>

Information to be reported . . .



Unless exempt:

- Chemical identity
 - Production volume
 - Method of manufacture, processing
 - Exposure and release information
 - Available physical – chemical, health effects and environmental impact data
- Small business – less than \$11 million when combined with parent corporation
 - Less than 1% of primary particles, aggregates, or agglomerates in the size range of 1-100 nm
 - Compounds that dissociate in water to form ions that are smaller than 1 nm
 - Chemical substances formed at the nanoscale as part of a film on a surface
 - Biological materials
 - Completed section 5 (new chemical) review since January 1, 2005

How can ANSI standards



existing nanomaterials?

- Composition (degree of purity, nature of impurities)
- Intrinsic properties (size, shape, surface area)
- Unique and novel properties
- Physical structure and topography
- Morphological changes
- Surface reactivity
- Zeta potential
- Dispersion stability
- Measured value for point of departure to assess changes greater than 7 times the standard deviation of the measured value
- Preparing the nanomaterial for biological testing

Law360 article

■ What Companies Should Know About TSCA Consent Orders

- *By Martha Marrapese, Partner in Wiley Rein LLP's Environment & Safety Practice in Washington, DC*
- Law360's Expert Analysis section, Oct. 27, 2017
- <https://www.law360.com/environmental/articles/972981/what-companies-should-know-about-tsca-consent-orders>





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