Responsible development of nanotechnology

Developing nanotechnology responsibly protects human health and the environment while realizing social and economic benefits. Responsible development addresses the design, use, and handling of nanomaterials throughout the product life cycle including end-of-life considerations. Responsible development of nanotechnology is an emerging chemical policy for states and includes environmental, health, and safety requirements, and best management practices.

Advancing green chemistry in Washington

In 2012, the Washington Department of Ecology (Ecology) in partnership with the Department of Commerce created A Roadmap for Advancing Green Chemistry in Washington State. A key feature of the roadmap promotes safer alternatives and product innovation. Emerging technologies and nanotechnology applications can play an important role in the development of safer and improved options for products across multiple sectors, including food, electronics, transportation, energy, medicine, material storage, and environmental remediation. The roadmap recognized "interdisciplinary cooperation is needed to achieve a better understanding of the potential risks of nanotechnology and the development of appropriate policies to address those concerns."

As product designers and consumers pursue better performance using safer materials, a degree of uncertainty exists about engineered nanomaterials. The scientific community, international governing bodies, and the green chemistry roadmap point out that nanomaterials often display unique properties distinct from the identical chemicals in bulk form.

Nanomaterial Defined

For this policy and to guide future actions, **nanomaterial** is defined as:

A material with any external dimension or internal structure of a size ranging from approximately 1 to 100 nanometers. The particles comprising a nanomaterial may be bound, unbound, aggregated, or agglomerated. Nanomaterials may be naturally occurring or engineered.

Examples of nanoscale internal structures:
- Tin oxide nanowires in flexible macro-sized thin-sheet anodes for advanced lithium ion batteries.
- Nano-sized diffraction gratings in some high-efficiency solar cells.
- Nanoscale pores in 3-D scaffolds for bone and tissue regeneration.

This definition of nanomaterial is a blend of definitions from the International Organization for Standardization (ISO), the European Commission, and the State of California.
An improved understanding of the transport, fate, bioavailability, and toxicity of nanomaterials will help determine whether nanotechnologies are viable green chemistry options, but a risk framework is needed to evaluate them. Guidance for risk evaluation of nanomaterials has not been adopted in Washington State or at the federal level. Nor has Washington State or the federal government said how nanomaterials fit into broader chemical management policies.

Toxicological tools that allow for rapid screening and alternative testing methods are in full development. However, without a chemical policy inclusive of new materials and risk evaluation guidance, the potential beneficial applications of nanomaterials cannot be fully integrated into the green chemistry roadmap.

After compiling a summary of ongoing actions within international governmental bodies, at the federal level, and at Ecology, this paper explores options and provides recommendations to address how Washington State can successfully integrate manufactured nanomaterials into the green chemistry roadmap.

**Summary of manufactured nanomaterial policy initiatives**

**International**

At the international level, the inclusion of nanomaterials in chemical management strategies is well underway. The United Nations Environmental Program adopted the Strategic Approach to International Chemical Management (SAICM) to move towards the production and use of chemicals, “in ways that minimize significant adverse impacts on the environment and human health.”2 One of the five key emerging policy topics in the strategic approach is nanotechnology. At its fourth international conference on chemical management held in the fall of 2015 in Geneva, a broad resolution specific to nanotechnology was adopted that encourages stakeholders to “address the sound management of manufactured nanomaterials.”

The Organization for Economic Cooperation and Development (OECD) is helping its member countries implement the SAICM. In 2007, it established the OECD Working Party on Nanotechnology.3 Much of the OECD efforts have focused on reviewing test methods for nanomaterial characterization and toxicological analyses.4 The European Commission’s Health Program, along with eleven member states, funded Nanogentox to establish methods for investigating the genotoxicity of nanomaterials. Various nations have nanomaterial registries, among them France, Belgium, and Denmark. South Korea has developed an inventory of nano-products.

**Federal**

In the United States, the Environmental Protection Agency (EPA) proposed a draft rule on April 6, 2015, for reporting and recordkeeping requirements for manufacturers or processors of certain nanomaterials. This action is based on Section 8(a) of the Toxics Substances Control Act (TSCA). The comments EPA received indicate that the EPA’s definition of nanomaterials is questioned. Some commenters argued that EPA does not have authority to require nanomaterial reporting because they do not clearly fall under the definition of “chemical substances.” With the ongoing TSCA reform, it is not clear how much more chemical management authority EPA will have or whether states will be pre-empted from pursuing their own regulatory efforts.

In October 2016, the U.S. National Science and Technology Council updated the National Nanotechnology Initiative (NNI) Strategic Plan.5 This document represents a consensus among the NNI agencies, including EPA, on the high-level goals and priorities to pursue over the next three years or more. This plan provides a framework that the states can use to address their own local needs.
In January 2017, EPA issued an information-gathering rule to ensure a better understanding of nanoscale materials in business. EPA issued a final regulation requiring one-time reporting and recordkeeping of existing exposure and health and safety information on nanoscale chemical substances in commerce under TSCA, section 8(a).

This rule requires companies to notify EPA if they manufacture, import, or process certain chemical substances already in commerce as nanoscale materials. The notification includes:

- Specific chemical identity.
- Production volume.
- Methods of manufacture, processing, use, exposure, and release information.
- Available health and safety data.

EPA will use this information to determine if further action under TSCA is needed, including additional information collection. Persons who manufacture or process a reportable chemical substance during the three years prior to the final effective date of this rule must report to EPA within a year of the rule’s publication.

**Washington State**

Ecology’s Hazardous Waste and Toxics Reduction (HWTR) Program has tracked scientific and policy developments in nanotechnology since 2008. Ecology was represented at the international SAICM meeting in 2015 where various nations presented their approaches to manufactured nanomaterial policy. Ecology is also:

- Sponsoring training events and webinars.
- Creating and managing the internal Emerging Technology SharePoint site.
- Compiling nanomaterial safety protocols for Ecology field staff.
- Interviewing academicians and other nanomaterial users and producers.
- Joining and participating with the American National Standards Institute (ANSI) Technical Committee 229 on Nanotechnology (TC-229), through Northwest Green Chemistry.

Ecology and the University of Washington co-led a journal club on the “Applications of International Data Standards Frameworks for Nanomaterials Risk Assessment.” The class reviewed major data standard frameworks for nanomaterials, including that of ISO. Three case studies were selected:

1. Nano-silver in sippy cups and pacifiers.
2. Micro- and nano-titanium in food products.
3. Fullerenes in face creams.

Case studies, including the information currently available in the literature, were discussed in the context of the ISO document 13121.

In 2016, Ecology purchased a Northwest Green Chemistry membership in the ISO ANSI TC 229 Technical Advisory Group. The membership gives experts in the Pacific Northwest an opportunity to interact with and provide input on international standards and reports. Collaborative work will help advance responsible nanotechnology and test method development. Northwest Green Chemistry members are particularly interested in the following topics:

- Environmental transport and fate of nanomaterials.
- Ecotoxicity of nanomaterials.
- Nanomaterial release into the environment during the product life cycle.
The Washington Green Chemistry Roadmap points to the need to “participate in regional and national green nanotechnology partnerships with industry, government, and NGOs to advance education and responsible nanotechnology development in Washington State.” Participation in the ANSI/TAG 229 has produced useful outcomes and should continue.

Another accomplishment from Ecology’s work with the ANSI TC-229 was introducing Dr. Robert Tanguay, a leading researcher in the development of zebrafish toxicological assays, to a South Korean research group interested in producing a standard method zebrafish assay. They are now jointly developing an international standard for zebrafish screening assays that will prove useful in nano-toxicology worldwide.

**Potential action plan for Washington State in fiscal year 2017-19**

As Washington State progresses towards a comprehensive chemicals policy, Ecology should develop a set of principles for managing chemicals responsibly including nanomaterials.

Ecology should integrate efforts of its Nanomaterials Work Group (NWG) into its Reducing Toxic Threats (RTT) initiative. The RTT initiative is Ecology’s key effort in adopting a comprehensive chemicals policy. One of NWG’s goals is to further integrate our work under the RTT banner. We recommend that the definition of “chemical substance” be clearly and broadly defined to include emerging materials as well as existing materials. Washington would also be well-served by collaborating with stakeholders to develop a set of principles for a comprehensive chemical management strategy. This strategy would:

- Support a framework for nanomaterial risk evaluation that promotes manufacturer responsibility to consider life cycles that prevent negative impacts to human health and the environment.
- Continue to track scientific and policy developments in nanotechnology and nano-toxicology.
- Continue to monitor and participate with the ANSI TC-229 through Northwest Green Chemistry.

**Budget and resource considerations over next biennium**


- Support Ecology’s NWG by helping to coordinate meetings and events, literature reviews, SharePoint organization, and similar tasks. The estimated cost for staff or intern at 0.05 FTE for 2 years is $11,000.

- Allocate staff time (0.1 FTE) to represent or coordinate NWG meetings, mentor intern, and track issues of importance. Ecology’s Jim Maroncelli of the Water Quality Program and Tom Boucher of the HWTR Program coordinate this workgroup.

**Other action items for consideration**

- Support a framework for nanomaterial risk evaluation promoting manufacturer responsibility in careful design with life-cycle considerations to prevent negative impacts to human health and the environment. Apply the relevant exposure assessment technologies being developed by the Harvard University School of Public Health. The framework should address environmental health and safety issues for manufacturers and consumers, and harmonize with the NNI Strategic Plan.
• Identify and attend relevant conferences or seminars on nanomaterials.

• Host a roundtable discussion with stakeholders to help create a set of nanomaterial principles for a comprehensive chemical management strategy in Washington. The estimated cost to retain a facilitator is $10,000, based on a series of five meetings plus inter-meeting coordination time. Since the outcome will affect most HWTR Program work, the cost may be shared with other program initiatives.

• Consider product-testing opportunities of children's and other consumer products. An estimated 0.2 FTE is needed for Quality Assurance Project Plan development and determining budget options.

• Water is emerging as an important focus both at the National Science Foundation (Food/Energy/Water nexus) and in the new NNI Strategic Plan. It is also becoming increasingly important from a geopolitical standpoint. Ecology's expertise should play a key role in the production and protection of clean water using nanomaterials.

• Develop external outreach materials, such as a website and focus sheets on issues and best practices.

• Participate as a stakeholder where appropriate to align Ecology environmental health and safety goals with Goal 4 of the U.S. NNI Strategic Plan and its sub-goals:
  Goal 4: Support responsible development of nanotechnology.

  4.1. Support the creation of a comprehensive knowledge base for evaluation of the potential risks and benefits of nanotechnology to the environment and to human health and safety.

  4.2. Create and employ means for timely dissemination, evaluation, and incorporation of relevant environmental, health, and safety knowledge and best practices.

  4.3. Develop the national capacity to identify, define, and responsibly address concepts and challenges specific to the ethical, legal, and societal implications of nanotechnology.

  4.4. Incorporate sustainability in the responsible development of nanotechnology.

Notes


