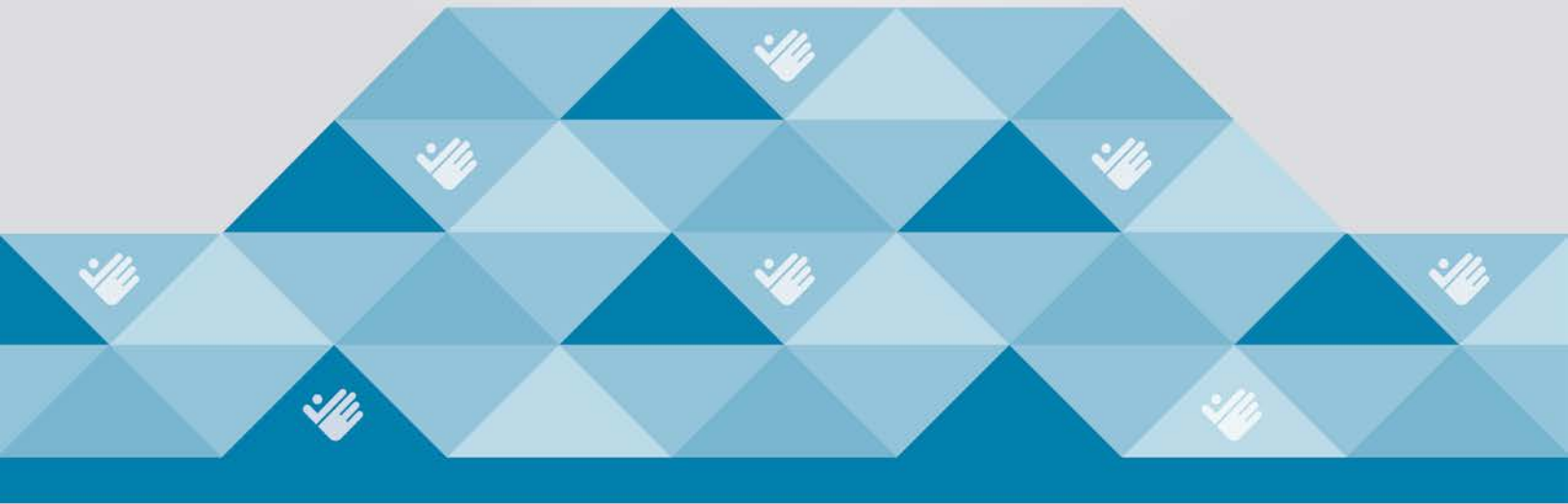


Nanomaterial Stewardship

*Guidance Sponsored by the
AIHA® Nanotechnology Working Group*

Approved by AIHA Board: March 15, 2017



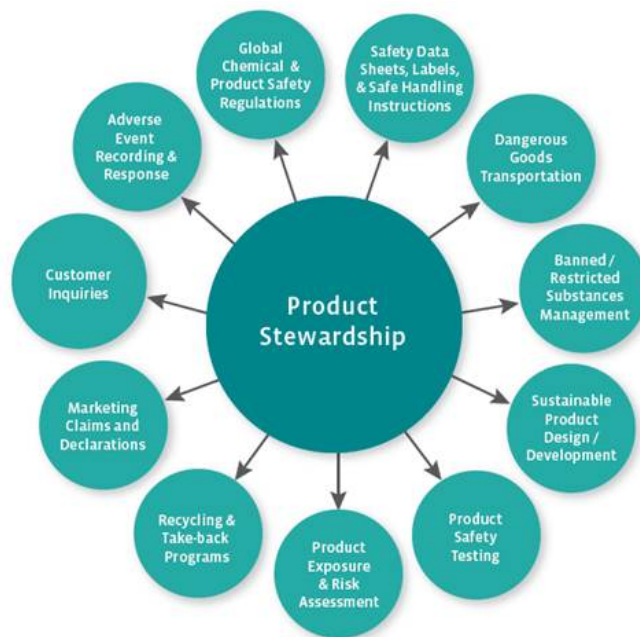
Nanomaterials (defined on next page) are being used to improve the performance of a rapidly-growing number of products. Examples include textiles that are bacteria resistant; composite building materials that are stronger and lighter; cosmetics that protect the skin; electronic equipment that is faster; sporting goods that are lighter; pharmaceuticals that are more effective; medical equipment that is more sensitive; energy production and storage that is cheaper and cleaner; and additives for fuels, inks, coatings, paints, and drilling and machining fluids that enhance performance.

In traditional roles, industrial hygiene and occupational safety professionals assess and manage potential risks to workers who handle nanomaterials. In businesses that produce or commercialize nanoparticles, nanomaterials, and/or nanoproducts, these professionals (along with product stewards and others) have the opportunity to apply relevant science and skills to anticipate, recognize, evaluate, and manage potential risks associated with nanoproducts throughout the product life cycle.

This guidance addresses stewardship for nanomaterials and their uses in products. See the AIHA fact sheet “Engineered Nanomaterials in the Workplace” for risk assessment and management guidance for workers.

Product stewardship is defined by the Product Stewardship Society as “responsibly managing the health, safety, and environmental aspects of raw materials, intermediate, and consumer products throughout their life cycle and across the value chain in order to prevent or minimize negative impacts and maximize value.”

The illustration to the right shows common product stewardship activities. This depiction reveals that industrial hygiene and safety professional skills for assessing and managing occupational risk can complement and support effective product stewardship, including stewardship for nanomaterials and nanoproducts. The following sections describe “nano” considerations for several of the product stewardship activities indicated.



NANO DEFINITIONS

While no universally accepted “nano” definitions exist for regulatory or for environmental, health and safety assessment and management purposes, the nano prefix in this context usually refers to a size range of approximately 1 to 100 nanometers (nm). Although 100 nm is not an upper size limit based on health risk, it is commonly used and has been adopted in some countries’ regulations. In other cases, nanoparticle definitions include a slightly larger particle size cutoff. In addition to size, some definitions also address the presence of nanoscale phenomenon, such as nanoscale quantum effects.

The following four general definitions are used for this guidance:

Nanoscale – size range from approximately 1 to 100 nanometers (nm).

Nanoparticle – any discrete piece of material with one or more external dimensions in the nanoscale. (Note that nanoparticles exist in many shapes. Some definitions also distinguish origin, i.e., whether the nanoparticles were intentionally engineered or manufactured vs. were incidentally produced vs. are naturally occurring. The term “ultrafine” is often used to describe nanoscale particles of incidental or natural origin.)

Nanomaterial – collective term for material containing nanoparticles, including for larger (>100 nm) particles made up of agglomerated (loosely associated; weakly bound) or aggregated (tightly bound or fused) nanoparticles.

Nanoproduct – collective term for commercialized products that contain nanoparticles or nanomaterials.

Regarding these and other nano definitions, do not assume that everyone has the same understanding of common terms. It is important to always establish the relevant definitions for regulatory compliance and even for the context of conversations with product stewards, environmental, health, and safety (EHS) professionals, analytical and materials scientists, product developers, material suppliers, customers and regulators.

LIFE CYCLE APPROACH

A product stewardship activity with much recent emphasis is sustainable product design and development. Important goals of a whole life cycle approach to sustainability ensure that potential EHS and regulatory impacts are:

1. Considered early in product and process design and development;



2. Addressed in product design, raw material selection, manufacture (including distribution operations), use (including maintenance), re-use, recycle, and disposal;
3. Reassessed periodically and when new information becomes available.

This ongoing, iterative review approach is especially important for emerging technologies since the science and regulations may still be evolving. To address overall sustainability attributes, relevant ethical, legal, and societal aspects should also be considered.

RAW MATERIALS FROM SUPPLIERS

It is important to have a process in place to systematically determine whether nanoscale ingredients are present in materials or products received from suppliers:

- Require suppliers to disclose nano content in their raw materials. For example, ask: “Does this material contain any nanomaterials with a primary particle size from 1 to 100 nanometers?”
- Enlist purchasing and product developers to alert the product steward and other EHS professionals, as appropriate, when there is intentional nanomaterial content in new product formulations.
- Review specification sheets, certificates of analysis, and other technical information sheets for materials with potential for nano-content.

Be aware that labels and Safety Data Sheets (SDSs) often do not accurately reflect nanomaterial content or hazards. See the Regulatory Landscape section of this guidance for information on improving nanomaterial SDSs.

SAFER DESIGN

Of particles: It may be possible to design (or select) safer nanoparticles by choosing or altering properties of the particles (such as composition, size, shape, crystal structure, surface characteristics, encapsulation, or functionalization). It may also be possible to reduce the amount of a hazardous nanomaterial needed to obtain the desired application functionality. Understanding characteristics of and reducing nanoparticle toxicity is an active field of research, as is the merging of green chemistry concepts with nanoscience.

Of manufacturing process: A producer of nanoparticles, nanomaterials, or nanoproducts may be able to develop safer synthesis or processing techniques or adopt existing



methods to reduce material hazard and/or potential for worker exposure. Examples of approaches that may reduce risk or hazardous waste are (1) using bottom-up synthesis methods free of hazardous catalysts vs. top-down methods and (2) using nanoparticles in liquid suspension vs. in dry powder form.

Of product: If a nanoparticle product is dispersive, it may be possible to reduce dispersion potential either by fixing the nanoparticles to other “support” ingredients or by modifying other ingredients that affect the dispersive nature to reduce exposure potential for end users. If nanoparticles are fixed in a product, the product design focus could be on reducing release of those nanoparticles during the product life cycle, for example, from wear, decomposition or corrosion during use, from abrasion during cleaning, or from grinding or shredding during recycling or disposal.

REGULATORY LANDSCAPE

Regulation affecting different nanoproduct life cycle stages drives or influences several product stewardship activities depicted earlier in this guidance. In general, many countries have mostly relied upon existing chemical and product EHS regulations to provide oversight for nanoparticles, nanomaterials and nanoproducts. Over time, some countries have either incrementally amended certain regulations (e.g., in Europe for cosmetics, for food and food packaging, and for pesticides/biocides), or have in some cases provided interpretation guidance documents for addressing nanomaterials with existing regulations.

When an original nano-specific regulation has been enacted, it has mainly taken the form of mandatory annual reporting of nanomaterials and/or nanoproducts into country inventories or registries to enable identification and tracking, and sometimes to prioritize future research or regulation. The country-by-country (and sometimes agency-by-agency) approach to regulation (with differences in scopes; nano definitions; and exemptions based on nanoparticle origin, persistence, product type, or other attributes) can result in complex compliance challenges. This is particularly true for companies whose nanomaterials or nanoproducts are manufactured, imported, distributed, or processed in multiple countries, or for a variety of applications, markets, and sectors covered by different agency jurisdictions.

It is important for product stewards and other EHS professionals to (1) identify which regulations apply to nanomaterials and nanoproducts they are responsible for (note that it is important to consider state and local as well as country regulations); (2) understand the requirements in detail; and (3) closely monitor the regulatory landscape for changes and new requirements potentially affecting commercialization.



Ensuring compliance with regulations is necessary for good product stewardship, but in the area of emerging technologies, specific regulation may not exist or keep up with the pace of innovation. Alongside mandatory requirements, various consensus standards or voluntary guidelines for behavior in the form of codes of conduct, position statements, white papers, and guidance for good practice have been developed by authoritative agencies, industry associations and other stakeholders, and those standards and guidelines may be useful to inform nanoproduct stewardship activities. An example is voluntary guidance intended to improve SDSs for nanomaterials.

Hazard communication regulation in many countries requires manufacturers and importers to provide hazard and safe use information for hazardous materials (at or above a designated percentage of composition) to downstream employers via SDSs to inform appropriate worker protection. Neither the United States Occupational Safety and Health Administration (OSHA) Hazard Communication Standard nor the European Union REACH and CLP regulations contain provisions specific to hazardous nanomaterials, but the definition of a chemical substance covers nanomaterials even if they are not specifically mentioned in the regulations. (REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals; CLP stands for Classification, Labelling and Packaging of substances and mixtures.)

Several studies have revealed that there is room for improvement regarding quality and completeness of nanomaterial SDSs, to enable effective risk assessment and management for downstream users when there is potential for human exposure from the release of nanoparticle content during reasonably anticipated use conditions. Improvement suggestions include:

1. Identify which ingredient(s) is nanoscale, and include size/size range information. (Because there is no harmonization regarding definition nor standardization for sample preparation, characterization and measurement methods for all nanoscale materials, additional information on these should be provided.)
2. Include known physical-chemical properties, such as nanoparticle shape, density, and solubility. (As above, it is important to reference methods.)
3. Indicate implications if the hazard classification, toxicity data, or occupational exposure limit provided was not derived from nanoscale material (for example, if classification is uncertain and may be incorrect; toxicity data may not be applicable; or exposure limit may not be protective for nanoscale material).

Simple suggestions for improving SDSs are not necessarily straightforward to carry out in practice. An advisory group to the United Nations Committee of Experts Sub-Group on the



Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is working to determine if amendments are needed to address hazard classification and SDSs for nanoscale forms of a substance. In the meantime, specific cautionary language about a nanoscale component could be added to any section where the data is appropriate. Another option is to use Section 16, Other Information.

Section 2.3 of a GHS SDS, Other Hazards Not Contributing to the Classification, could also be useful. For example, in the United States, OSHA has created a combustible dust hazard class that might be applicable to certain nanoparticles (based on material physicochemical properties and tendency to readily become and stay airborne). General guidance for SDSs and labels is available from standards organizations such as ANSI, and nanomaterial-specific guidance has also been published (e.g., by the International Organization for Standardization).

In summary, based on the lessons of past product liability claims related to non-nanomaterial chemical content, it is prudent to consider both regulatory requirements and product stewardship related guidelines or industry standards of practice during nanoproduct commercialization. In the context of litigation, a duty to leverage existing guidance may be expected, even if the guidance is non-mandatory.

PRODUCT EXPOSURE AND RISK MANAGEMENT

Many guidance documents and tools have been developed to help with assessing and controlling worker exposure to nanoparticles, which in some cases may have a hazard profile different from that of larger particles of similar composition. Some of this guidance is also relevant for nanomaterial and nanoproduct producers striving to understand potential downstream user risk and determine appropriate risk management measures prior to commercialization.

Some of the same issues that challenge industrial hygiene and occupational safety professionals conducting exposure and risk assessment in the workplace will also be challenges for upstream suppliers of nanoparticles, nanomaterials, and nanoproducts conducting assessments of hazard and potential for exposures during other product life cycle phases. Examples of these challenges include:

1. Insufficient characterization of nanoparticle content and potential changes (Particle characteristics and thus hazard characteristics may change during the product life cycle.)
2. Insufficient toxicity data to assess health hazards or develop exposure limits for the exposed population(s)



3. Insufficient information in published toxicity studies to determine relevance and reliability (e.g., insufficient particle characterization information and/or level of detail provided on study methods to extract, disperse, and dose nanoparticles)
4. Uncertainty regarding an appropriate metric (e.g., particle mass, size distribution, count, surface area, or surface activity) for the material and exposure situation
5. Lack of standardized and validated sampling and analytical methods, and difficulties with data interpretation (See the AIHA fact sheet “Nanoparticle Sampling and Analysis.”)
6. Limited ability to accurately and repetitively simulate exposure scenarios relevant for myriad product applications, and insufficient characterization of same in published literature

Given these many challenges, nanoproduct exposure and risk assessment studies have often focused on the apparently simpler question of whether nanoparticles may be released during intended and foreseeable uses, maintenance, recycling, or disposal. In these scenarios, questions to be answered include:

What is released?

- Are released particles the “pristine” ingredient particles or have particle physical-chemical characteristics changed? (Such changes may lead to a different toxicity profile or different exposure potential.)
- Are the nanoparticles integrated within or bound to other material or other particles? (Exposure or health risk profile may be affected.)
- Can the nanoparticle of interest be distinguished from background or other interfering material released, such as from other materials or tools used with the product? (Need to understand limitations of sampling and analytical methods and results interpretation.)
- To what extent are nanoparticles aggregated or agglomerated? (This can affect how the particles behave in air and if or where they deposit in the respiratory tract.)



How much is released?

- What are the appropriate metric(s) and method(s) to measure release? (Particle mass, count, surface area, chemical composition, etc.)
- What are important variables? (e.g., substance, amount in product, the way particles are incorporated, use conditions)

Under what conditions are particles released?

- Consider typical use vs. extreme use, aging/weathering, washing, UV light exposure, sanding, abrasion, etc.

Might cross-contamination of nano-free products occur?

- During washing of nano-textiles, mixing of recycled materials, etc.

Even the apparently simpler nanoparticle release approach to determining exposure potential can clearly be quite complex.

Guidance and additional information are available in the Resources section.

Acknowledgments

This document represents a compilation of information from the valuable input of the members of the AIHA Nanotechnology Working Group and others. Major contributors were **Rena Goldman**, CIH, FAIHA, **John Baker**, CIH, **Charles Geraci**, PhD, CIH, FAIHA, **Michele Shepard**, PhD, CIH, **John Lowe**, CIH, and **Christine Knezevich**, CIH.

KEY POINT SUMMARY

- Consider EHS and regulatory impacts through the entire nanoproduct life cycle, and start early in development. Apply safer design principles to particles, processes, and products.
- Chemical hazard communication regulations apply, and there may be applicable country, state, and/or local requirements for nanomaterials and nanoproducts. Determine which requirements apply and monitor regulatory changes.
- State-of-the science continues to evolve for hazard, exposure, and risk assessment.

RESOURCES

AIHA fact sheets and guidance related to nanomaterials:

<https://www.aiha.org/government-affairs/Pages/Position-Statements-and-Resources.aspx>.

AIHA Nanotechnology Working Group web page for additional resources related to nanomaterial product stewardship: <https://www.aiha.org/get-involved/VolunteerGroups/Pages/Nanotechnology-Working-Group.aspx>

Baker, J., M. Barrie, C. Geraci, and M. Hoover: Soft law and nanotechnology. *Synergist* 27 (4):30–33. <http://synergist.aiha.org/201604-soft-law-and-nanotechnology>.

Bergeson & Campbell, P.C.: Nano and Other Emerging Chemical Technologies Blog (monitors regulatory and policy status globally). <http://nanotech.lawbc.com/about>.

European Commission Joint Research Centre Science and Policy: *Considerations on Information Needs for Nanomaterials in Consumer Products* (Report). 2014. http://publications.jrc.ec.europa.eu/repository/bitstream/JRC88931/reqno_jrc88931_considerations_information_needs_nm_consumer_products_online.pdf.

International Organization for Standardization. *Nanomaterials – Preparation of Material Safety Data Sheet* (Publication no. 13329:2012). December 2012. For purchase at http://www.iso.org/iso/catalogue_detail.htm?csnumber=53705.

Nanoscale Science, Engineering, and Technology Subcommittee and Nanotechnology Environmental and Health Implications Working Group: *Quantifying Exposure to Engineered Nanomaterials (QEEN) from Manufactured Products – Addressing Environmental, Health, and Safety Implications* (Report). U.S. National Nanotechnology Initiative, March 2016. <http://www.nano.gov/node/1584>.

Product Stewardship Society. <http://www.productstewards.org/Resources/Pages/default.aspx>.

U.S. Department of Health and Human Services (NIOSH): *Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small to Medium-Sized Enterprises* (Publication no. 2016–102). March 2016.

Section 5: Prevention through Design

Section 11: Product Stewardship

Section 12: Federal Regulatory Compliance

<http://www.cdc.gov/niosh/docs/2016-102/pdfs/2016-102.pdf>.



