

[OECD Future Challenges Related to the Safety of Manufactured Nanomaterials: Report From The Special Session \(Workshop Report\)](#)

Outlines the comprehensive challenges for addressing manufactured nanomaterial safety.

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for the 11/04/2016 report.



WHAT IT DOES

The Organization for Economic Co-operation and Development ([OECD](#)) is an intergovernmental organization comprised of 34 democracies with market economies and 70 other non-member economies that collaborate to promote economic growth, prosperity, and sustainable development. The OECD held a special session on [Future Challenges Related to the Safety of Manufactured Nanomaterials: Report from the Special Session](#), which acknowledges the remaining challenges to [manufactured nanomaterials](#) (MNs) safety assessment:

- Applicability of [OECD Test Guidelines](#) - [Physicochemical](#) validation through repeated data acquisitions will be critical to ensuring the applicability of proposed regulations and policies.
- Assessment methods and tools - Methods that can read across groups of [nanomaterials](#) and can assist in [alternative testing](#) development and [adverse outcome pathways \(AOPs\)](#).
- Exposure data - Data that accurately depict on-site nanomaterial exposures and product-based exposures will be necessary for nanomaterial modeling.
- Guidance materials to assist with the interpretation of data - Consolidation of data wherein criteria can be assigned for quality assurance and creation of better analytical tools.

Based on this OECD workshop, parties concluded that the best means to minimize challenges that complicate MN safety assessments is to adapt existing regulatory structures to address challenges spawned from MNs. Doing so must include:

- Determining where existing regulatory frameworks can be applicable to nanomaterials regulation. For example, the [Registration, Evaluation, Authorization, and Restriction of Chemicals \(REACH\)](#) protocols, used within the European Union, has been found appropriate for MN regulation with the aid of OECD Test Guidelines.
- Homing in on physicochemical factors that dominate nanomaterial behavior. For instance, the United States Environmental Protection Agency (EPA) suggests that materials that exhibit a change in at least the [zeta potential](#), [specific surface area](#), [dispersion stability](#), or [surface reactivity](#) should be reported as a potential nanoscale material.
- Advanced toxicological methodologies, such as [Integrated Testing Strategies \(ITS\)](#), that integrate different types of data, wherein appropriate weights can be provided to each form of evidence, will enhance the decision-making processes established on current regulatory paradigms.

To this end, the meeting experts acknowledge and support that:

- Members of the Working Party on Manufactured Nanomaterials (WPMN) must address critical issues that span delegates' interests, such as [validation](#), to advance OECD Testing Guidelines within the allotted resources. Each delegate is bound by unique economic resources, and lofty goals could overburden each delegate's capacity.
- The need for guidance materials grounded in substantiated evidence persists.
- Emphasis should be given to the need for calculation aids, which could assist metric conversions during data processing.
- WPMN members should collaborate with other organizations to achieve validation and policy [harmonization](#) to minimize overlap

and duplication of efforts.

- Efforts to develop alternative testing methods, acquire exposure data, and formulate approaches to risk assessment should be encouraged. While financial constraints limit delegates' attentions to necessities, the WPMN has been commissioned to balance such interests.

This workshop determined that the benefits of categorization of manufactured nanomaterials include:

- Enhanced prediction of MN toxicity;
- Novel methods to [characterize](#) nanomaterials that bridge existing gaps;
- Well-informed decisions that incorporate MN data and [nanomaterial-related risk management](#);

Guidelines that can be generalized across multiple delegates.

RELEVANT SCIENCE

Chemical substances with structures that measure approximately 1 – 100 nanometers (nm) along at least one dimension are often referred to as nanomaterials, or nanoscale materials. The nanoscale is thousands of times smaller than the unaided human eye can see. [Nanomaterials](#) may have a similar chemical composition, meaning that the samples contain a similar ratio of [elements](#), however their shapes (or morphologies) may be different, which causes them to exhibit different behaviors or [properties](#). Nanomaterials have a greater amount of surface area when compared weight per weight with materials at a larger scale (also known as the bulk scale). More surface area suggests a lot more reactions may take place on nanomaterial than on bulk scale material surfaces, hence an increase in surface reactivity at the nanoscale. Greater chemical reactivity can be either a useful feature or might cause harm. For example, nanoscale materials have the potential to enhance the efficiency of a [battery](#), to [detect](#) or [treat cancer cells](#), or measure whether [insulin level](#) is abnormal. However, some nanomaterials can enter human cells (or coat them) and alter normal functions, thereby causing cellular dysfunction or perhaps permanent damage.

There is not one type of nanomaterial or a specific nanomaterial behavior that may be attributed to all nanomaterials. Experts think that groups of materials may have predictable behaviors, however, they have yet to reach a consensus regarding how they should be categorized. All nanomaterials cannot be tested for every possible environmentally relevant and human health related assessment using release, exposure, or hazard studies. The extensive number of various measurements and the tremendous number of nanomaterials to be tested as well as the need to coordinate scientists on a global scale to devote years to complete such a task are nearly insurmountable obstacles. Moreover, after data collection and organization into searchable databases, cross-comparative analyses would be required to identify trends among the various nanomaterials under various conditions. There is need for the development of some method(s) of grouping that will allow comparison of behaviors-of-interest, as well as to evaluate the potential exposure risks associated within the different nanomaterial groups.

WHY IT MATTERS

The predominant goal of the WPMN is to provide relevant guidelines for nanomaterial assessment that are mutually accepted by an international community. The presentations summarized in the current [workshop report](#) highlight the demand for advancements in the nanomaterials community that reduce disparity between delegates' observations. In conjunction with the inherent difficulties of characterizing nanomaterials, the inconsistency amongst delegates' observations stymies nanomaterial-enabled products and processes. This complexity negatively impacts technology-centric economies wherein significant funding has been invested. Of interest to the OECD and associated regulators are [regulatory frameworks](#) that are adequate for all delegates within the OECD community. The lack of political synchronization revolving around MNs could lead to the use of independent frameworks developed by each respective delegate, which would require industry participants to abide by different standards. While such a scenario would not be unprecedented, the paradigm may discourage entrance of nanomaterial-enabled products into the global economy.

Furthermore, scientific and technological barriers common to WPMN delegates steer research towards areas-of-interest regarding

publicly-funded studies and private sector research and development. Efforts to overcome the barriers have the potential to dilate new areas of scientific and economic interest that could lead to invention and innovation. For example, the current [special report](#) emphasizes that conversion tools, novel testing strategies, and superior characterization techniques are prerequisites to [safe by design](#) approaches elusive to industry. This conclusion may encourage scientists and engineers to focus their ingenuity towards software for metric conversions, novel [in vitro](#) or [in silico](#) testing methods, or innovative [nanoscale techniques](#). Therefore, the [75th workshop report](#) not only identifies organizational and regulatory commonalities of delegates from the initiation of the WPMN to its current state, but the summary also promotes ingenuity and industrial involvement that aim to repair observational inconsistencies. Synergy between national and international parties serves to optimize research productivity and expedite MN policies that can be integrated into trade policies within the global economy.

RELEVANT EXPERTS

[Mike Hochella, Ph.D.](#), University Distinguished Professor of the Virginia Tech Department of Geosciences; Director of the Virginia Tech National Center for Earth and Environmental Nanotechnology Infrastructure ([NanoEarth](#)); Affiliate Professor of the Center for the Environmental Implications of NanoTechnology ([CEINT](#)) Duke University.

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BACKGROUND

The Organization for Economic Co-operation and Development ([OECD](#)) is an intergovernmental organization, which is comprised of 34 countries within the regions of North and South America, Europe, and Asia-Pacific. OECD delegates collaborate to protect human and environmental health, through meeting and responding to international and mutual policy issues of concern spanning the scientific fields of chemicals, pesticides and biotechnology. An underlying goal of the OECD has been to establish the Working Party on Manufactured Nanomaterials (WPMN), which attempts to address the current state of manufactured nanomaterials (MNs) active in industry and assess their properties to guide nanomaterial-associated policies. The WPMN has provided a series of workshops that aim to provide better frameworks for description and prediction of the toxic effects of nanomaterials as they interact with biological and environmental systems throughout their lifecycles. Because MNs have the potential to impact standards of living and quality of life through a variety of processes such as, catalysis in chemical production, energy efficiencies of devices, advanced delivery of therapeutics, and through [other means](#), their integration will result in many complex chemical and physical interactions that can be context-dependent. Although the WPMN is inherently an international group, it is comprised of delegate members that are bound by constraints dictated by their respective governments. OECD parties have designated common challenges that are keys for efficient resource allocation. Commonalities amongst the WPMN delegates have been difficult to pinpoint, an effect further complicated by the intricacies of nanomaterial description and the diversity of metrics submitted by delegate members.

ENDORSEMENTS & OPPOSITION

The [Nanotechnology Environmental and Health Implications \(NEHI\)](#) working group is a branch of the [Nanoscale Science, Engineering, and Technology \(NSET\)](#) subcommittee that spawned from the [National Nanotechnology Initiative \(NNI\)](#). The NEHI is devoted to “Working with international organizations and governments to share information on and to develop strategies for nanotechnology environmental, health, and safety research,” as well as “supporting the development of tools and methods to identify, prioritize, and manage strategies for specific research to enable risk analysis and regulatory decision-making for nanomaterials and products incorporating nanomaterials.”

Despite being focused around the clinical aspects of nanotechnology, previous workshops have concluded that harmonized policies have been associated with diminished technological activity. For example, debate between experts that has been provided in [Nanotechnology and Oncology: Workshop Summary](#) noted that clinical activity regarding nanomedicines had reduced in response to the harmonization of United Kingdom policies with stringent European directives. Furthermore, it was stated that “overregulation of clinical research in the United Kingdom has reduced productivity without enhancing safety.” The workshop was geared specifically towards nanomedicine, however, the potential for the same effect to cross into other sectors involving nanotechnology remains prevalent. Ensuring that harmonization of national and international policies does not hinder the development of nanotechnology while simultaneously promoting safe practices will continue to be a complicated issue.

No opposition has been published about this subject by nanomaterials’ scientists.

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RECOMMENDED CITATION

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