OECD Categorization of Manufactured Nanomaterials (Workshop Report)

Recommends standards for the categorization of nanomaterials.

Updated last **May 16, 2017**
for the 2/17/16 Workshop Report.

WHAT IT DOES

The Organization for Economic Co-operation and Development (OECD), which is an intergovernmental organization comprised of 35 countries that collaborate to promote policies that will improve the economic and social well-being of people around the world, held a workshop for the Categorization of Manufactured Nanomaterials. The purpose of the OECD Series on the Safety of Manufactured Nanomaterials is to provide up-to-date information on the OECD activities related to human health and environmental safety.

The OECD has been working to influence the field of nanomaterials on a global scale to: (1) agree on how to categorize nanomaterials; (2) develop standards for nanomaterial property measurements as well as functional assays (or the means of measuring how nanomaterials behave/react under various conditions); and (3) assess how exposure to nanomaterials pose risks to human health and ecosystem stability as well as exposure management.

One of the overarching goals of the OECD global initiative is to move the nanoscience field toward collection and analysis of scientific information about manufactured nanomaterials to assist in regulations development. Although there is growing evidence that some applications of nanotechnologies may be capable of solving some of humanities most difficult issues, such as, cleaning up the environment, reforming the ozone layer, providing cheap, clean water for millions of people, and producing methods of effectively treating previously incurable illnesses, industries have already introduced nanomaterials into consumer products without adequate knowledge of the potential implications for human and environmental health.

Categorization of nanomaterials is difficult. Nanomaterials may have similar composition yet have different shapes (morphologies) that alter their properties and their behaviors. Nanomaterials are not forever stable – they do not forever retain the same composition, shape, surface area, or behavior. As consumer products age and degrade, nanomaterials contained within them may be released (e.g. nano-silver particles embedded into clothing, nanowires woven into fabric, encapsulated nanoparticles or coated nanoparticles, batteries, cell phones, and computer components); as such, there is risk that they will potentially become exposed to the environment or to humans. Thus, the workshop report proposes categorization methods that must include:

- Physical-chemical properties - Physical-chemical properties of nanomaterials alone are not enough to group or categorize nanomaterials, because different nanomaterials will exhibit different behaviors from other nanomaterials when exposed to similar environments, even if they have some similar properties (e.g. composition, surface area, shape);
- Lifecycle (or potential for release), whether the nanomaterials are separate entities or part of some manufactured product - The nanomaterial lifecycle tells us about the potential for release into the environment where the nanomaterials may then be exposed to people, pets, wildlife, or to some larger ecosystem;
- Fate and transport - Movement of manufactured nanomaterials through the environment is the fate or transport properties in a particular environment;

- Exposure risk assessment - Risk assessments and exposure studies inform us of the hazards of manufactured nanomaterials that get released and, perhaps, transported through the environment; and
- Risk management - Risk management includes the means by which a regulatory entity exerts its influence to govern or manage manufactured nanomaterials policy in industry to ameliorate the potential risk to workers, consumers, and to the environment.

Based on this OECD workshop, parties concluded that the current best means of categorization of manufactured nanomaterials is a fit-for-purpose framework that will be suitable for different regulatory programs. These must include:

1. Identifying and developing, where needed, methods for characterization of relevant physical-chemical properties for release, fate, hazard, and exposure assessments.
2. Use of methods that enable comparability and reliability
3. Agreeing on or developing experimental models, such as *in-vitro* (in a test tube) and *in-vivo* (in a living organism) assays that are predictive of human health and environment effects and that support grouping.

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

1. Techniques used for grouping manufactured nanomaterials might be different depending on the criteria for the assessment (e.g., risk, exposure, nanomaterial form).
2. Definitions will need to be clarified, updated, and consistently applied.
3. Case studies will be used to evolve and refine grouping schemes.
4. Existing approaches will need to be adapted for manufactured nanomaterial substances to fit into updated groupings.

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

- Limiting the amount of data and testing required;
- Improving assessments of exposure risks posed to workers;
- Reducing the uncertainty about exposure risk assessments; and

Allowing regulators to focus on acquiring new data, as need be, and subsequently making adjustments to science policies.

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

Not only do the properties of nanomaterials make them challenging, from the perspective of exposure and risk assessment, but the countless assemblages of building blocks that make up the nanomaterial, their shapes and structures, and the presence of surface coatings can affect manufactured nanomaterial behavior and, as such, their behavior in the environment and in humans (or other living creatures). The behavior of manufactured nanomaterial exposed to various environments/organs/tissues can be altered from that of the original nanomaterial as they easily may be modified by exposure to other chemicals in their local environments. Thus, making predictions about manufactured nanomaterial behavior and their resulting affects and risks becomes very challenging. Likewise, due to the numerous variety of manufactured nanomaterials and their differing properties, it is difficult to identify nanomaterials or classes of nanomaterials that may behave similarly with respect to fate, transport, toxicity, and risk management. Moreover, there has been significant disparity among standardized materials and methods that evaluate research on nanomaterial exposure. Taking all of the known issues into account, there is motivation for a categorization strategy to address the critical gaps between nanoscience and regulation.

Currently, more than 150 OECD test guidelines, which distinguish different material types that assess the potential effects of chemicals on human health and the environment, are used in a legally binding agreement between all of the cooperating governments within the Organization for Economic Cooperation Development (OECD). Additionally, this workshop report indicated certain nanomaterials of particular industrial importance that should be considered priority for individual chemical testing to which there was quick response by the OECD Testing Program of Manufactured Nanomaterials. The fact that currently there is no general consensus on the definition of a nanomaterial, either nationally or internationally, poses future challenges related to the safety of manufactured nanomaterials. The overarching goal of this workshop report was to develop and define categorization of nanomaterials using a scientific approach as well as to improve the decision-making process for regulatory purposes.

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. In 2005, the OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology held a Special Session on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety. Over the past decade, there have been eighty workshop reports (including the current report) toward building a collaborative organization, examining the progress in our understanding of nanomaterial exposure, risk, and management assessments, and decisions about best methods of standardized measurements.

ENDORSEMENTS & OPPOSITION

The Nanotechnology Industries Association (NIA) actively works for nanomaterial safety by participation in global fora like the Organisation for Economic Co-operation and Development (OECD). The NIA believes in the "[p]romotion of science- and technology-based support for the safe and reliable advance and commercialisation of nanotechnologies is a core aim for NIA. Particularly important in achieving this is advanced cooperation both within the industrial community and between all stakeholders of nanotechnologies, in order to ultimately secure the societal and environmental benefits of nanotechnology."

As pointed out by David Koepsell in The Morality of Risk: A Primer, "Regulation has had its failures. Sometimes safety and security issues are poorly understood and not appropriately anticipated. Regulating authorities may focus on irrelevant features of the technologies or unlikely risks. Moreover, the costs associated with regulation, both economic and social, may be greater than those associated with the risks. Regulating too much too early may be needless, yet failing to identify real hazards or harms can be disastrous."

RELATED POLICIES

- EPA Reporting and Recordkeeping Requirements of Chemical Substances when Manufactured or Processed as Nanoscale Materials (Final Rule),
- Frank R. Lautenberg Chemical Safety for the 21st Century Act (Public Law 114-182), Swedish Chemical Agency (KEMI) Nanomaterials Reporting (Proposed Rule), and
- Nanotechnology Advancement and New Opportunities Act (HR 4865, 114th Congress).

ORGANIZATIONS

The members as well as the sponsoring agencies that contributed to this OECD report described here are available for viewing and download (pp 99-106).

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RECOMMENDED CITATION

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