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AIHA Comments on the National Nanotechnology Initiative (NNI) Environmental, Health, and Safety (EHS) Research Strategy

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Dear Ms. Murphy:

AIHA, the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety (OEHS), appreciates the opportunity to provide feedback on the National Nanotechnology Initiative's Environmental, Health, and Safety Research Strategy. We hope you find our feedback useful and are happy to answer any questions you may have.

1. What are the research accomplishments in the following six core research areas identified in the 2011 NNI EHS Strategy? The six core research areas are (1) Nanomaterial Measurement Infrastructure, (2) Human Exposure Assessment, (3) Human Health, (4) Environment, (5) Risk Assessment and Risk Management Methods, and (6) Informatics and Modeling.

AIHA fully supports research in the core research areas identified in the NNI EHS Strategy,

Over the years, various successful continuing databases and nanoscience research centers have been made available, including the following:

- The cancer Nanotechnology Laboratory (caNanoLab) is a data-sharing web portal designed to facilitate information sharing across the international biomedical nanotechnology research community to expedite and validate the use of

nanotechnology in biomedicine.[1] focuses on nanotechnologies related to biomedicine.

- The NanoMaterials Registry, maintained by RTI International[2], an independent nonprofit research institute.
- Duke University's Center for the Environmental Implications of NanoTechnology (CEINT), Knowledge Commons (NIKC)[3] and their NanoDatabank. CEINT[4] performs fundamental research on the behavior of nano-scale materials in laboratory and complex ecosystems. "Research includes all aspects of nanomaterial transport, fate and exposure, as well as ecotoxicological and ecosystem impacts. Additionally, CEINT is developing risk assessment tools to provide guidance in assessing existing and future concerns surrounding the environmental implications of nanomaterials."[5]
- The NanoSafety Cluster a harmonized approach to European research in nanotechnology is a series of projects funded by the European Commission, an infrastructure for toxicological data management of engineered nanomaterials.[6] Information on the related eNanoMapper database for nanomaterial safety can be found at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4578352/
- U.S. Naval Research Laboratory (NRL) Institute for Nanoscience, which "conducts innovative, multidisciplinary research at the intersections of the fields of materials, electronics, and biology in the nanometer size domain."[7] NRL's research is primarily sponsored by the Office of Naval Research, Naval Systems Commands and Warfare Centers, Air Force, Army, DARPA, Department of Energy, and NASA.

Nanomaterial measurement infrastructure accomplishments include identifying uses of nanomaterials in material science for example construction engineering requires materials that enhance the mechanical properties of the composites for modern concrete infrastructure. "Cement-based materials can be mixed with nanomaterials such as nano-silica (nano-SiO2), nano-alumina (nano-Al2O3), nano-ferric oxide (nano-Fe2O3), nano-titanium oxide (nano-TiO2), carbon nanotubes (CNTs), graphene and graphene oxide."[8]

[1] https://cananolab.cancer.gov/
[2] https://www.rti.org/about-us
[3] https://ceint.duke.edu/research/nikc
[4] https://ceint.duke.edu/about
[5] Ibid.
[6] https://www.nanosafetycluster.eu/
[7] https://www.nrl.navy.mil/nanoscience/
[8] https://doi.org/10.3390/ma12213548

2. What research gaps remain in addressing the six NNI EHS core research areas listed in question 1?

Significant nanomaterial measurement infrastructure gaps exist

The OEHS practitioner community still lacks affordable and reliable nanoparticle measurement methods, primarily direct reading instruments or integrated monitors, that can provide a more accurate measure of human exposure, primarily inhalation exposure. Evaluating the impact on workers and public health more completely will require more techniques that can be made readily available beyond very complex laboratory-based instruments. Measurements made during actual human exposure scenarios will need to be correlated with exposure dose measurements made during toxicology studies, and that remains a gap. Methods to measure nanomaterials released from nano-enabled products also remains a gap.

Human exposure assessment needs

Nanomaterials continue to be used in growing quantities as an enabling ingredient. Unfortunately, relatively little data are available on the actual human exposures that occur during the synthesis, manufacture, formulation or processing of engineered nanomaterials. Industrial sectors such as construction, plastics, electronics, and surface coatings are high-volume users of nanomaterials or nanomaterial enabled products, yet exposure assessment data are lacking. Agricultural use of nanomaterials is also increasing dramatically and there are little or no data regarding actual exposure among agriculture workers. Exposure from consumer products needs to go beyond lab testing and deployed via public health professionals.

Human health

More studies are needed in the areas of dermal exposure and its impact as well as neurotoxicology of nanomaterials, and the impact on toxicity (hazard) of nanomaterials at various points along the supply/value chain. More effort is needed to create and incentivize human exposure surveillance and health outcomes. There is a distinct opportunity to tie the EHS research outputs of nanotechnology to many of the questions and concerns being expressed regarding ultrafine particulate in the environment, including micro and nanoplastics.

More research, direction and information are also needed for stakeholders on how to communicate nanoproduct hazards especially in Safety Data Sheets when the product's toxicological information is lacking or unknown.

3. The ethical, legal, and societal implications (ELSI) of nanotechnology are considered across the core research areas of the 2011 strategy. What additional ways could ELSI be more fully integrated throughout a refreshed NNI EHS research strategy?

The full spectrum for ethical and legal implications of nanotechnology is currently unknown. Research is needed in this area for identifying the possible legal, ethical and societal implications of nanotechnology for example in artificial intelligence, and nanoproduct legal and ethical issues. Currently, nanomaterials have been introduced for biocides, cosmetics, food additives, food labelling and materials in contact with foodstuffs. Nanotechnologies also imply ethical questions. The main problems are public trust, potential risks, issues of environmental impact, transparency of information, responsible nanoscience, and nanotechnologies research.

One under-studied area of ethical concern is the use of nanomaterials in agriculture. Little is known about the impact of increasing the overall presence (burden) of nanomaterials as pesticides or nutrient carriers in food production.

4. What broad themes should the revised strategy adopt to integrate and connect the six research areas?

Nanoscience is a broad field encompassing many different disciplines. The themes can be broken into broad areas with the fields identified for each broad theme.

The NNI agencies should collaborate more closely on extending the definition of 'nanotechnology' to recognize the growing body of advanced materials, ultrafine particles in general, and the interface between nano, advanced, and biological systems. Biomanufacturing is a good example of this.

The NNI agencies should continue identifying strategies for conducting risk assessments, risk management methods, and nano-informatics that will expedite the integration of information from human exposure assessments (including worker), ecotoxicological testing, and human health modeling to provide chemical regulators with the tools necessary to enable them to evaluate new nanomaterials and advanced materials. Without better strategies and methods, regulators are having to conduct risk evaluations on a "one by one" basis for new nanomaterials and advanced materials. A robust, science-based set of bridging principles (e.g., read across techniques that account for different physiochemical properties of nanomaterials and advanced materials) will be needed so that we can responsibly manage nanomaterials and advanced materials without impeding the wide scale adoption of these new materials.

5. How should the updated NNI EHS research strategy reflect the evolution of nanotechnology beyond engineered nanomaterials to complex systems, structures, and devices?

As nanoscience evolves, new questions will arise regarding the evolution of this field. As more becomes understood, new questions will become more apparent with complex biological and chemical systems we have not developed yet. A provision should be made regarding how these complex systems will be integrated into development of a more complete understanding.

As noted above, the evolution of advanced materials and material systems, both chemical and biological, will call for a broader view of health, safety, and environmental implications. This research should not be constrained by a single definition of a material or a material characteristic.

The NNI agencies should consider expanding their nanomaterial focus to include submicron advanced materials that have unique and novel properties. In commercial research, engineered materials with unique and novel properties drift into and outside of the nanoscale range depending on the desired material properties. Many advanced materials began as engineered nanomaterials designed to have specific characteristics. As additional performance data was collected, the mean particle sizes of these engineered nanomaterials increased above 100 nm to optimize the desired properties of these new materials. Technically these materials are no longer engineered nanomaterials, as their mean particle sizes are greater than 100 nm and less than 1 micron. However, the original engineered "unique and novel properties" of these materials still needs to be responsibly managed.

6. The 2011 strategy focused on engineered nanomaterials and did not include incidental nanoscale materials such as nanoplastics and certain nanoscale particulate emissions such as those from 3D printing. If the updated strategy is revised to include some non-engineered or incidental nanomaterials, describe how to scope the strategy in a way that complements rather than being redundant with existing health and environmental research (e.g., by excluding the large body of existing research on air pollution, which can include nanoscale particles).

The revised national nanotechnology field should include all nano products with the integration of all nanoscale particulate emissions, including 3D printing. For example, Fused Filament Fabrication has been established as a widely practiced additive manufacturing technique, using various thermoplastics. Exposure data regarding novel materials and larger scale operations is, however, still lacking.[9]

[9] https://www.mdpi.com/2504-477X/6/5/119

The revised strategy should develop a plan to use existing knowledge on ultrafine particulate and expand research opportunities to include occupational and general public health implications. Ultrafine (nanoscale) emissions from a wide range of industrial processes should be included in a more holistic view of health protection, worker wellbeing, and general public health. A wealth of information was developed by NNI agencies for engineered nanomaterials and that knowledge should be used to gain a better understanding of ultrafine particulate impact.

Conclusion

If you have any questions about AIHA's responses to updates on the National Nanotechnology Initiative's Environmental, Health, and Safety Research Strategy, please contact me at mames@aiha.org or (703) 846-0730. Thank you for your time and consideration.

Sincerely,

Mark Ames
Director, Government Relations
AIHA

About AIHA

AIHA is the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety in the workplace and community. Founded in 1939, we support our members with our expertise, networks, comprehensive education programs, and other products and services that help them maintain the highest professional and competency standards. More than half of AIHA's nearly 8,500 members are Certified Industrial Hygienists, and many hold other professional designations. AIHA serves as a resource for those employed across the public and private sectors as well as to the communities in which they work. For more information, please visit https://www.aiha.org/.