Concept Clearance

Branch: Exposure Response and Technology Branch

Council Period: 201605

Concept Title: Center for Safety Implications for Nanotechnology in Consumer Products

Introduction

The Nanotechnology industry is recognized as a major economic force in the 21st century with an estimated output of about $1.5trillion with the use of engineered nanomaterials (ENMs) in thousands of consumer products. Projections are that the field will continue to grow at a very high rate with the continued development of new engineered nanomaterials with novel physicochemical properties. The number of consumer products containing ENMs has increased significantly over the past five years with titanium, silver, and carbon-based ENMs the most widely used materials. This widespread use of ENMs in consumer products, including products intended for use by young children may result in exposures to ENMs. As outlined in the 2011 White House Memorandum: Policy Principles for the U.S. Decision Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials outlined the need for federal agencies to utilize a risk based approach to understanding nanomaterial implications, including exposure along with potential hazards along the life-cycle. Thus, it is critical that stakeholders including federal agencies, manufacturers and distributors of nano-enabled products have robust tools and methods to characterize these potential exposures and any potential health impacts.

The Consumer Product Safety Commission (CPSC) is the Federal Agency with primary responsibility for addressing human exposure to chemicals, including nanotechnology (nanomaterials) that are contained in consumer products. With this rapid growth of consumer products in the market, both CPSC staff and manufacturers must assess potential risks though robust methods to characterize and quantify nanomaterials in products, their release from the products, or human exposures and related health effects. Currently, there is a clear lack of reliable data on identifying new products containing ENMs and information on consumer use and interaction with these products once they are introduced into the marketplace. To evaluate the potential risk of ENMs in the general population or in occupational settings, it is extremely important to understand the real-world exposure scenarios and specific classes and characteristics of materials in consumer products. The knowledge gained from toxicology studies (such as those in the Nanotechnology Health Implications Research (NHIR) program) can be utilized in the context of population studies to assess potential risks and health impacts. To gain comprehensive understanding from exposure to health risks there is a need for a collaborative multidisciplinary team of researchers with wide ranging expertise from material science, chemistry, toxicology, epidemiology and predictive risk modeling. Towards this goal and at the request of Congress, the CPSC and NIEHS are proposing to partner to develop the Center for Safety Implications for Nanotechnology in Consumer Products.

The proposed concept outlines collaborative efforts between CPSC and NIEHS to address potential human health effects due to unintended or intended exposure to ENMs from a diverse consumer products ranging from blast resistant back bags to antimicrobial sprays and construction materials.

This research program also addresses components of NIEHS Strategic Goals 1, 3 and 5.

The overarching goal of the Center for Safety Implications for Nanotechnology in Consumer Products is to gain understanding on the potential health implications and risks resulting from exposure to ENMs in consumer products. This requires a tiered product life-cycle based approach that includes qualitative and quantitative evaluation of ENMs hazard, exposure potential and toxicity to determine human risk. Due to the multidisciplinary nature of the expertise and collaboration required, this can be achieved by a multi-project center aimed at addressing four key knowledge gaps in consumer product safety assessment: 1. Types and characteristics of ENMs in consumer products; 2. Real-world use and lifecycle of products to assess human exposure; 3. Inventories of diverse consumer products to understand factors (physical, human and environmental) affecting release of ENMs and associated public perception; and 4. Human exposure assessment. This center will also have one administrative core and an analytical support core.

Project 1. Characterization of ENMs in consumer products:

Due to proprietary nature of nanomaterial commercialization, there is often a lack of information on the types and characteristics of ENMs used in the consumer products. To quantify human exposure to ENMs, characterizing the type and amount of ENMs present in the product and characterize its composition, physical and chemical properties, and whether its present as freely dispersed or bound to matrix is critical. This involves developing and validating diverse test methods and techniques for identification, quantification and characterization of ENMs in the products. Such a comprehensive characterization requires access to and expertise to use diverse spectroscopy methods (Mass, ICP-MS, IR, FT-IR, affinity purification), optical imaging methods (Raman, LSCM) and higher analytical methods for characterization- SEM, TEM, electron energy loss

spectroscopy to gain knowledge on individual ENM properties, coupled with statistical analysis to predict bulk properties as well as product-level nanomaterial characterization.

Project 2. Real-world use and Life Cycle Analysis of Consumer products:

To gain understanding of the potential exposure to ENMs in the consumer products, an exhaustive evaluation of realistic scenarios for material release for individual product types based on their intended and real-world use as well as misuse. The release mechanism may vary depending on the type of ENMs and the matrix. Example questions could include:

- ENMs release from products containing composites such as textiles, paint and coating on exposure to UV light?
- The effects of mechanical or temperature stress on cookware or sporting equipment;
- Quantifying release of ENMs intentionally added to foods such as organic nano-capsulates incorporating flavor?
- Migration of ENMs from personal care products through skin?
- Quantification of release of ENMs from aerosolization of personal care products or cleaning products?

This project will investigate how methods and techniques used for quantifying ENMs in products can be refined to assess release of ENMs. These efforts are aimed at developing a standardized (QA and QC) set of test methods for consumer product-specific ENMs release.

Project 3. Develop inventories of diverse consumer products to understand factors (physical, human and environmental) affecting release of ENMs and associated public perception:

Developing robust exposure methods requires a basic understanding of the range of materials used in consumer products, the specific nano-enabled products, and the components and matrices (e.g., plastic) containing the nanomaterial. The product type and matrix may significantly impact the use characteristics and the mechanisms for nanomaterials release. Products such as toys may undergo daily mastication by children while a tennis racquet may be subject to intermittent use by more mature consumers. Nanomaterials released from these products may be free particles or bound in a matrix in varying degrees. Fundamental research is needed to understand how these human factors may impact release and subsequent exposure to consumers. Consumer perception of the safety of nanomaterials may significantly impact the number of products in commerce, the degree to which they are used, and the population subgroups exposed to nano-enabled products must be understood.

4. Human exposure assessment:

Accurate assessment of human exposure to ENMs from consumer products is confounded by complexity, diversity and variation of ENMs, product matrices, use and environmental conditions. This is further confounded by exposure pathways, transformation of ENMs, altered properties and fate. But, there are a number of fundamental processes governing the release and fate of ENMs from products. This project will aim to develop methods and tools for detection of ENMs in biological samples and their associated physicochemical properties –

- Distribution (size) and chemical speciation,
- Distinguishing between individual nanomaterials and population of nanomaterials;
- Distinguish ENMs from background (anthropogenic) nanoparticles.
- Tools to monitor personal exposure to ENMs (that distinguish from anthropogenic ambient ultrafine particles)

The resulting data can then be used to inform the development of models to predict the exposure pathways from consumer products to human exposures.

Administrative Core

An Administrative Core staff will be responsible for overall planning, managing, coordinating, and supervising the entire range of Center activities, including monitoring progress, and ensuring that a strategic plan is implemented in an effective and efficient manner.

Analytical Core

This core will provide laboratory support for developing and/or provide capabilities for characterization of ENMs in consumer products and in biological media and the environment. May also serve as a resource for developing QA and QC methods for measurement and characterization of nanomaterials in new consumer products nominated CPSC or manufacturers.

Mechanism and Justification
This funding opportunity will utilize U54 mechanism. Due to the multiple project and multidisciplinary nature of this center there will be an active participation of NIEHS and CPSC program staff in developing milestones and deliverables. In addition, an external advisory committee will also provide scientific and programmatic oversight to this center.