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Contractor Task Description Versar Nanomaterial Toxicity Assessment

#### 1. Background

There is a growing use of compounds or materials that have been produced using technologies (i.e., nanotechnologies) that directly manipulate matter at the atomic level and fabricate materials that could not have been produced in the past. Nanomaterials are defined as materials/particles that range from 1 to 100 nm in length. Although these materials may have the same chemical composition as non-nanomaterials, these new materials may demonstrate different physical and chemical properties; and they may behave differently in the environment and in the human body.

In the conference report on H.R. 4040, CPSIA of 2008, in its discussion on the authorization of appropriations (Section 201), Congress stated that it recognizes nanotechnology as a new technology utilized in the manufacture of consumer products, and that the Conferees expect the Commission to review the utilization and safety of its application in consumer products consistent with the Commission's mission.

In FY'08 the U.S. Consumer Product Safety Commission (CPSC) initiated an Interagency Agreement with the National Institute for Occupational Safety and Health (NIOSH) to evaluate the particulate aerosol generated during use of an antimicrobial spray product containing  $TiO_2$  nanoparticles. The tests have been completed and confirmed the presence of nanoparticles in the aerosol spray. In 2009, the CPSC signed an IAG with NIST to quantify releases of carbon nanotubes that are used as flame retardants from treated mattress and upholstered furniture components. The CPSC has also signed an IAG with NIOSH and EPA to study the release of nanosilver from a variety of products including those used by young children.

#### 2. Objective

The objectives of this task are to review all of the existing data relating to the toxicity of nanosilver, nanotitanium, and carbon nanotubes.

#### 3. Description of Task

The Contractor shall provide documents that will include overviews of toxicological properties of nanoscale and non-nano Ag and TiO2, with a focus on nanoparticles of these materials, and overviews of information on nano-sized particles of carbon and a focus on carbon nanotubes. Single-walled and multi-walled carbon nanotubes will be discussed separately.

The contractor will:

- Evaluate pertinent toxicokinetic, toxicological, and mechanistic studies, including in vitro studies into potential mechanisms of action for nano materials.
- Identify NOAELs and LOAELs from pertinent toxicology studies,
- Draw conclusions about the weights of evidence associating exposure (by pertinent exposure routes to be determined with CPSC) with health hazards

• Draw conclusions about the suitability of the available data for deriving ADIs for specific substances within the three classes of materials. This analysis will include examining the apparent critical effects identified from the available data and what might be prospective principal studies for ADI development.

Derivation of ADIs will include rationales for selection of the critical effect(s), principal study(ies), and points of departure. The ADIs will be for chronic duration of exposure, and will be based on a NOAEL/LOAEL approach. The contractor will provide proposals and rationales for uncertainty factors in the areas of 1) animal to human extrapolation, 2) human variability, and 3) extrapolation across duration (e.g., subchronic to chronic).

# 4. Deliverables or Performance

The Contractor shall provide the requested information in the form of a written report to the CPSC Project Officer within (90) days after the initial teleconference or meeting. The report shall be in the format of a scientific report with full citations, tables, and figures as appropriate. The reviewer shall e-mail the report to the Project Officer in a Microsoft Word (preferred) or WordPerfect file.

Item(s)	Quantity	Delivery or Performance
The CPSC Project Officer and	1	June 2009
Contractor will meet by		
teleconference or in person to		
discuss and initiate the project		
The CPSC Project Officer will be available to consult with	As appropriate	At the completion of each subtask, or monthly,
the Contractor by		whichever comes first.
teleconference or in person.		
The Contractor shall submit	1	Within 10 days after the initial
aan outline of the final report		teleconference or meeting
to the CPSC Project Officer		
The Contractor shall submit a	1	Within 90 days after the
draft final report to the CPSC		phthalates are selected in
Project Officer.		consultation with the CPSC Project Officer.
The CPSC Project Officer will	1	Within 30 days after receipt of
provide written comments on		the draft final report.
the draft final report to the		_
Contractor.		
The Contractor shall submit a	The Contractor will revise the	Within 30 days after receipt of
final report to the CPSC	draft final report as	comments.
Project Officer.	appropriate.	
Inspection and Acceptance	The Final report will be	Within 30 days after receipt of

# 5. Delivery Schedule





reviewed by the CPSC Project	the report
Officer	_

# 6. Place of Delivery

U.S. Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814

CPSC Project Officers and contact information:

Treye A. Thomas, Ph.D. tthomas@cpsc.gov 301-504-7738

## 7. Inspection and Acceptance

The Draft Final Toxicity Review report submitted to the U.S. Consumer Product Safety Commission will be reviewed within 30 days of receipt of the draft final report for any additional questions and/or comments. If returned to the Contractor as a result of the review, the Contractor shall address and/or revise their report accordingly and return the final version to the Project Officer within 30 days of receipt. The CPSC Project Officer will then have an additional 30 days to review the Final Toxicity Review report.

## 8. Requirement for CPSC Clearance

The final report is the property of the U.S. Consumer Product Safety Commission. The Contractor will not publish the final report, present the information at scientific meetings, or in any other way make the findings public in any form without the written permission of the Project Officer. Any publication must be cleared following CPSC procedures, as outlined in the Consumer Product Safety Act.

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