IAA-15-EL-04

United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
General Terms and Conditions (GT&C) Section

IAA Number CPSC-I-15-0032 (GT&C #) - 0000 - (Order #) _____ (Amendment/Mod #)

DEPARTMENT AND/OR AGENCY			
1.		Requesting Agency of Products/Services	Servicing Agency Providing Products/Services
	Name	U.S. Consumer Product Safety Commission 4330 East West Highway	USACE Engineer Research and Development Center
	Address	Division of Procurement Services, Room 523, Bethesda, MD 20814-4408	3909 Halls Ferry Road Vicksburg, MS 39180

2. Servicing Agency Agreement Tracking Number (Optional) _____

3. Assisted Acquisition Agreement Yes ☐ No ☑

4. GT&C Action (Check action being taken)

☑ New

☐ Amendment – Complete only the GT&C blocks being changed and explain the changes being made.

☐ Cancellation – Provide a brief explanation for the IAA cancellation and complete the effective End Date.

5. Agreement Period Start Date 09-01-2015 (MM-DD-YYYY) End Date 12-16-2016 (MM-DD-YYYY) of IAA or effective cancellation date

6. Recurring Agreement (Check One) A Recurring Agreement will continue, unless a notice to discontinue is received.

Yes ☐ If Yes, is this an: Annual Renewal ☐

Other Renewal ☐ State the other renewal period: _____

No ☑

7. Agreement Type (Check One) ☑ Single Order IAA ☐ Multiple Order IAA

8. Are Advance Payments Allowed for this IAA (Check One) ☐ Yes ☑ No

If Yes is checked, enter Requesting Agency's Statutory Authority Title and Citation

Note: Specific advance amounts will be captured on each related Order.

IAA-EL-15-04

United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
General Terms and Conditions (GT&C) Section

IAA Number CPSC-I-15-0032 (GT&C #) - 0000 - (Order #) _____ (Amendment/Mod #)

9. **Estimated Agreement Amount** (The Servicing Agency completes all information for the estimated agreement amount.)
(Optional for Assisted Acquisitions)

Direct Cost	$720,000.00
Overhead Fees & Charges	
Total Estimated Amount	$720,000.00

Provide a general explanation of the Overhead Fees & Charges

10. STATUTORY AUTHORITY

a. Requesting Agency's Authority (Check One)

Franchise Fund	Revolving Fund	Working Capital Fund	Economy Act (31 U.S.C. 1535/FAR 17.5)	Other Authority
☐	☐	☐	☐	☑

Fill in Statutory Authority Title and Citation for Franchise Fund, Revolving Fund, Working Capital Fund, or Other Authority
Section 27(g) of the Consumer Product Safety Act, 15 (U.S.C. 2076(g))

b. **Servicing Agency's Authority** (Check One)

Franchise Fund	Revolving Fund	Working Capital Fund	Economy Act (31 U.S.C. 1535/FAR 17.5)	Other Authority
☐	☐	☐	☑	☐

Fill in Statutory Authority Title and Citation for Franchise Fund, Revolving Fund, Working Capital Fund, or Other Authority

11. **Requesting Agency's Scope** (State and/or list attachments that support Requesting Agency's Scope.)
This Interagency Agreement (IAG) establishes an agreement between the CPSC and the US Army Engineer Research and Development Center (ERDC) to develop innovative tools for measuring the potential health impact of nanotechnologies used in consumer products and develop risk prioritization models for exposure to materials released from these consumer products. The project will be based on the prior work conducted by ERDC and other members of the National Nanotechnology Nanotechnology Knowledge Infrastructure (NKI; see: http://www.nano.gov/NKIPortal) to integrate, manage, and use a wide range of nanomaterial data.

12. **Roles & Responsibilities for the Requesting Agency and Servicing Agency** (State and/or list attachments for the roles and responsibilities for the Requesting Agency and the Servicing Agency.)
The Consumer Product Safety Commission (CPSC) will provide guidance on the selection of information intended for the database, criteria for data curation, and provide comments on the user interface for the visualization tool. The CPSC will also provide guidance on the selection of products for further testing and the selection of toxicity tests used for evaluating hazard. The development of the prioritization tool will require expert judgment input from CPSC.
The US Army Engineer Research and Development Center (ERDC) will provide the expertise to develop the database, provide expertise for the data curation, and expertise for the development of models. The ERDC will conduct the testing and analysis of products containing nanomaterials and include any relevant collaborations required to complete the work.

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Interagency Agreement (IAA) – Agreement Between Federal Agencies
General Terms and Conditions (GT&C) Section

IAA Number CPSC-I-15-0032 - 0000 - _____
GT&C # Order # Amendment/Mod #

13. Restrictions (Optional) (State and/or attach unique requirements and/or mission specific restrictions specific to this IAA).

14. Assisted Acquisition Small Business Credit Clause (The Servicing Agency will allocate the socio-economic credit to the Requesting Agency for any contract actions it has executed on behalf of the Requesting Agency.)

15. **Disputes:** Disputes related to this IAA shall be resolved in accordance with instructions provided in the Treasury Financial Manual (TFM) Volume I, Part 2, Chapter 4700, Appendix 10; Intragovernmental Business Rules.

16. **Termination** (Insert the number of days that this IAA may be terminated by written notice by either the Requesting or Servicing Agency.)

30

If this agreement is canceled, any implementing contract/order may also be canceled. If the IAA is terminated, the agencies shall agree to the terms of the termination, including costs attributable to each party and the disposition of awarded and pending actions.

If the Servicing Agency incurs costs due to the Requesting Agency's failure to give the requisite notice of its intent to terminate the IAA, the Requesting Agency shall pay any actual costs incurred by the Servicing Agency as a result of the delay in notification, provided such costs are directly attributable to the failure to give notice.

17. Assisted Acquisition Agreements – Requesting Agency's Organizations Authorized To Request Acquisition Assistance for this IAA. (State or attach a list of Requesting Agency's organizations authorized to request acquisition assistance for this IAA.)

18. Assisted Acquisition Agreements – Servicing Agency's Organizations authorized to Provide Acquisition Assistance for this IAA. (State or attach a list of Servicing Agency's organizations authorized to provide acquisition for this IAA.)

19. Requesting Agency Clause(s) (Optional) (State and/or attach any additional Requesting Agency clauses.)

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United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
General Terms and Conditions (GT&C) Section

IAA Number CPSC-I-15-0032 - 0000 - _____
GT&C # Order # Amendment/Mod #

20. **Servicing Agency Clause(s)** (Optional) (State and/or attach any additional Servicing Agency clauses.)

21. **Additional Requesting Agency and/or Servicing Agency Attachments** (Optional) (State and/or attach any additional Requesting Agency and/or Servicing Agency attachments.)

22. **Annual Review of IAA**

By signing this agreement, the parties agree to annually review the IAA if the agreement period exceeds one year. Appropriate changes will be made by amendment to the GT&C and/or modification to any affected Order(s).

AGENCY OFFICIAL

The Agency Official is the highest level accepting authority or official as designated by the Requesting Agency and Servicing Agency to sign this agreement. Each Agency Official must ensure that the general terms and conditions are properly defined, including the stated statutory authorities, and, that the scope of work can be fulfilled per the agreement.

The Agreement Period Start Date (Block 5) must be the same as or later than the signature dates.

Actual work for this IAA may NOT begin until an Order has been signed by the appropriate individuals, as stated in the Instructions for Blocks 37 and 38.

23.	Requesting Agency	Servicing Agency
Name	Eddie Ahmad	Beth C. Fleming, PhD
Title	Contracting Officer	Director, Environmental Laboratory
Telephone Number(s)	(301) 504-7884	(601) 634-3943
Fax Number	(978) 244-8640	
Email Address	aahmad@cpsc.gov	Beth.Fleming@usace.army.mil
SIGNATURE	AAhmad Digitally signed by AAhmad DN: c=CPSC, ou=HO, ou=EXAD, cn=AAhmad Date: 2015.08.24 12:55:57 -04'00'	
Approval Date		

IAA-15-EL-04

United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

IAA Number CPSC-I-15-0032 - _____ - _____ Servicing Agency's Agreement Tracking Number (Optional) _____
GT&C # Order # Amendment/Mod #

PRIMARY ORGANIZATION/OFFICE INFORMATION		
24.	Requesting Agency	Servicing Agency
Primary Organization/Office Name	U.S. Consumer Product Safety Commission	USACE Engineer Research and Development Center
Responsible Organization/Office Address	Division of Procurement Services, Room 523, Bethesda, MD 20814	3909 Halls Ferry Road Vicksburg, MS 39180

ORDER/REQUIREMENTS INFORMATION

25. Order Action (Check One)

☑ **New**

☐ **Modification** (Mod) – List affected Order blocks being changed and explain the changes being made. For Example: for a performance period mod, state new performance period for this Order in Block 27. **Fill out the Funding Modification Summary by Line** (Block 26) if the mod involves adding, deleting or changing **Funding for an Order Line.**

☐ **Cancellation** – Provide a brief explanation for Order cancellation and fill in the Performance Period End Date for the effective cancellation date.

26. Funding Modification Summary by Line	Line # _____	Line # _____	Line # _____	Total of All Other Lines (attach funding details)	Total
Original Line Funding	$720,000.00	$	$	$	$720,000.00
Cumulative Funding Changes From Prior Mods [addition (+) or reduction (-)]	$	$	$	$	$0.00
Funding Change for This Mod	$	$	$	$	$0.00
TOTAL Modified Obligation	$720,000.00	$0.00	$0.00	$0.00	$720,000.00
Total Advance Amount (-)	$	$	$	$	$0.00
Net Modified Amount Due	$720,000.00	$0.00	$0.00	$0.00	$720,000.00

27. Performance Period Start Date 09-01-2015 (MM-DD-YYYY) End Date 12-16-2016 (MM-DD-YYYY)

For a performance period mod, insert the start and end dates that reflect the new performance period.

IAA-15-EL-04

United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

IAA Number CPSC-I-15-0032 - _____ - _____ (GT&C # / Order # / Amendment/Mod #)
Servicing Agency's Agreement Tracking Number (Optional) _____

28. Order Line/Funding Information		Line Number _____
	Requesting Agency Funding Information	**Servicing Agency Funding Information**
ALC	61-00-0001	000-8736
Treasury Agency Code	61150100	
Trading Partner Code	DUNS: 069287522	
TAS	61-0100	97 X 2015 0400
BETC	DISB	COLL
Object Class Code (Optional)	TIN: 520978750	
BPN		DOD964424
BPN + 4 (Optional)		
Additional Accounting Classification/Information (Optional)	0100A15DSE 2015 2370400000 EXHR004200 255A0 - $720,000.00	DUNS:098165889 EIN: 62-1642142

Requesting Agency Funding Expiration Date	Requesting Agency Funding Cancellation Date
09-30-2015 (MM-DD-YYYY)	09-30-2020 (MM-DD-YYYY)

Project Number & Title: Impact of Material Matrix on Nanomaterial Toxicity - Development of Risk Models for Exposure to Materials Released from Consumer Products

Description of Products and/or Services, including the Bona Fide Need for this Order (State or attach a description of products/services, including the bona fide need for this Order.)
This Interagency Agreement (IAG) establishes an agreement between the CPSC and the US Army Engineer Research and Development Center (ERDC) to develop innovative tools for measuring the potential health impact of nanotechnologies used in consumer products and develop risk prioritization models for exposure to materials released from these consumer products.

North American Industry Classification System (NAICS) Number (Optional) _____

Breakdown of Reimbursable Line Costs

Unit of Measure		
Quantity	Unit Price	**Total**
		$0.00
Overhead Fees & Charges		$
Total Line Amount Obligated		$0.00
Advance Line Amount (-)		$
Net Line Amount Due		$0.00

OR Breakdown of Assisted Acquisition Line Cost:

Contract Cost	$
Servicing Fees	$
Total Obligated Cost	$0.00
Advance for Line (-)	$
Net Total Cost	$0.00

Assisted Acquisition Servicing Fees Explanation

Type of Service Requirements

☐ Severable Service ☑ Non-severable Service ☐ Not Applicable

IAA-15-EL-04

United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

IAA Number CPSC-I-15-0032 - _____ - _____ Servicing Agency's Agreement
GT&C # Order # Amendment/Mod # Tracking Number (Optional) _____

29. Advance Information (Complete Block 29 if the Advance Payment for Products/Services was checked "Yes" on the GT&C.)

Total Advance Amount for the Order $_____ [All Order Line advance amounts (Block 28) must sum to this total.]

Revenue Recognition Methodology (according to SFFAS 7) (Identify the Revenue Recognition Methodology that will be used to account for the Requesting Agency's expense and the Servicing Agency's revenue)

☐ Straight-line – Provide amount to be accrued $_____ and Number of Months _____

☐ Accrual Per Work Completed – Identify the accounting posting period:

☐ Monthly per work completed & invoiced

☐ Other – Explain other regular period (bimonthly, quarterly, etc.) for posting accruals and how the accrual amounts will be communicated if other than billed.

30. Total Net Order Amount: $720,000.00
[All Order Line Net Amounts Due for reimbursable agreements and Net Total Costs for Assisted Acquisition Agreements (Block 28) must sum to this total.]

31. Attachments (State or list attachments.)

☐ Key project and/or acquisition milestones (Optional except for Assisted Acquisition Agreements)

☐ Other Attachments (Optional)

BILLING & PAYMENT INFORMATION

32. Payment Method (Check One) [Intra-governmental Payment and Collection (IPAC) is the Preferred Method.]
If IPAC is used, the payment method must agree with the IPAC Trading Partner Agreement (TPA).

☐ Requesting Agency Initiated IPAC ☑ Servicing Agency Initiated IPAC
☐ Credit Card ☐ Other – Explain other payment method and reasoning.

33. Billing Frequency (Check One)

[An Invoice must be submitted by the Servicing Agency and accepted by the Requesting Agency BEFORE funds are reimbursed (i.e., via IPAC transaction)]

☑ Monthly ☐ Quarterly ☐ Other Billing Frequency (include explanation)

34. Payment Terms (Check One) Net 30

☐ 7 days ☑ Other Payment Terms (include explanation): _____

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United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

IAA Number CPSC-I-15-0032 - _____ - _____ Servicing Agency's Agreement Tracking Number (Optional) _____
GT&C # Order # Amendment/Mod #

35. Funding Clauses/Instructions (Optional) (State and/or list funding clauses/instructions.)

36. Delivery/Shipping Information for Products (Optional)	
Agency Name	USACE ERDC-Environmental Lab
Point of Contact (POC) Name & Title	Jeffery Steevens, PhD
POC Email Address	jeffery.a.steevens@usace.army.mil
Delivery Address /Room Number	3909 Halls Ferry Road, Vicksburg, MS 39180
POC Telephone Number	(601) 634-4199
Special Shipping Information	

APPROVALS AND CONTACT INFORMATION

37. PROGRAM OFFICIALS
The Program Officials, as identified by the Requesting Agency and Servicing Agency, must ensure that the scope of work is properly defined and can be fulfilled for this Order. The Program Official may or may not be the Contracting Officer depending on each agency's IAA business process.

	Requesting Agency	Servicing Agency
Name	Treye Thomas, Ph.D.	Beth C. Fleming, PhD
Title	Lead Toxicologist	Director, Environmental Laboratory
Telephone Number	(301) 978-2560	(601) 634-3943
Fax Number		
Email Address	tthomas@cpsc.gov	Beth.Fleming@usace.army.mil
SIGNATURE	Treye Thomas	
Date Signed		

38. FUNDING OFFICIALS - The Funds Approving Officials, as identified by the Requesting Agency and Servicing Agency, certify that the funds are accurately cited and can be properly accounted for per the purposes set forth in the Order. The Requesting Agency Funding Official signs to obligate funds. The Servicing Agency Funding Official signs to start the work, and to bill, collect, and properly account for funds from the Requesting Agency, in accordance with the agreement.

	Requesting Agency	Servicing Agency
Name	James Baker	Maria Ehmann
Title	Budget Officer	Budget Officer, USACE ERDC
Telephone Number	(301) 504-7575	(217) 373-6745
Fax Number		
Email Address	jbaker@cpsc.gov	maria.a.ehmann@usace.army.mil
SIGNATURE	jbaker@cpsc.gov	EHMANN.MARIA.ANN.1230436262
Date Signed		

IAA-15-EL-04

United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

IAA Number CPSC-I-15-0032 - _____ - _____ Servicing Agency's Agreement
GT&C # Order # Amendment/Mod # Tracking Number (Optional) _____

CONTACT INFORMATION		
FINANCE OFFICE Points of Contact (POCs) The finance office points of contact must ensure that the payment (Requesting Agency), billing (Servicing Agency), and advance/accounting information are accurate and timely for this Order.		
39.	**Requesting Agency (Payment Office)**	**Servicing Agency (Billing Office)**
Name	Debbie Young	Kevin Heath
Title	Payment Officer	USACE Finance Center Director
Office Address	CPSC Accounts Payable Br, AMZ-160 PO Box 25710, Oklahoma City, OK 73125	5722 Integrity Drive Millington, TN 38054
Telephone Number	(405) 954-7467	(901) 874-8535
Fax Number		(901) 874-8572
Email Address	9-AMC-AMZ-CPSC-Accounts-Payable@fa	Kevin.j.heath@usace.army.mil
Signature & Date (Optional)		
40. ADDITIONAL Points of Contacts (POCs) (as determined by each Agency) This may include CONTRACTING Office Points of Contact (POCs).		
	Requesting Agency	**Servicing Agency**
Name	Eddie Ahmad	
Title	Contracting Officer	
Office Address	4330 East West Highway Bethesda, MD 20814-4408	
Telephone Number	(301) 504-7884	
Fax Number	(978) 244-8640	
Email Address	aahmad@cpsc.gov	
Signature & Date (Optional)	AAhmad	
Name		
Title		
Office Address		
Telephone Number		
Fax Number		
Email Address		
Signature & Date (Optional)		
Name		
Title		
Office Address		
Telephone Number		
Fax Number		
Email Address		
Signature & Date (Optional)		

IAA-15-BL-0

CPSC-I-15-0032
INTERAGENCY AGREEMENT
BETWEEN THE
U.S. CONSUMER PRODUCT SAFETY COMMISSION (CPSC)
AND THE
US ARMY ENGINEER RESEARCH AND DEVELOPMENT CENTER (ERDC)

1. TITLE

Impact of Material Matrix on Nanomaterial Toxicity - Development of Risk Models for Exposure to Materials Released from Consumer Products

2. PARTIES AND PURPOSE

This Interagency Agreement (IAG) establishes an agreement between the CPSC and the US Army Engineer Research and Development Center (ERDC) to develop innovative tools for measuring the potential health impact of nanotechnologies used in consumer products and develop risk prioritization models for exposure to materials released from these consumer products. The project will be based on the prior work conducted by ERDC and other members of the National Nanotechnology Knowledge Infrastructure (NKI; see: http://www.nano.gov/NKIPortal) to integrate, manage, and use a wide range of nanomaterial data.

3. BACKGROUND

Nanotechnologies are used in globally sold consumer products (e.g., electronic computer housing, soft furnishings, and cosmetic products) to meet the market's and consumer's performance and cost requirements. Many of the experimental nanotechnologies developed over the last decade have been evaluated by manufacturers, and a few (e.g., carbon nanofibers and nanotubes) are being or are planned to be incorporated into consumer products. In 2005, the CPSC released a nanomaterial statement identifying the need for both toxicity and exposure data, in order to adequately address the risks associated with nanomaterial use in consumer products. Since 2011, the CPSC has developed several interagency agreements to develop robust methods to characterize and quantify the presence and release of nanomaterials in consumer products.

The CPSC has also relied on other federal agencies such as the National Institute for Environmental Health Sciences (NIEHS) and Environmental Protection Agency (EPA) to develop toxicity data. The data identified by other agencies typically use pristine nanomaterials in testing protocols, while CPSC's mission requires data that focuses on consumer exposure. Consumers are expected to be exposed to nanomaterials that are released from products; those products will likely contain nanomaterials that will be attached to, or are encapsulated by, the product matrix (i.e., plastics). CPSC's mission requires data that thoroughly characterizes exposure, and determines the impact the material matrix may have on nanomaterial uptake into the body and the ultimate effects of these materials.

Similar to CPSC requirements, the DoD has significant uncertainty regarding the environmental health and safety (EHS) effects of the products or technologies containing nanomaterials. Much remains unknown regarding how nanomaterials behave, including questions about the nature of nanoparticles vs. nanostructures, nano vs. bulk materials, whether nanomaterials are more or less toxic than chemically similar dissolved or bulk material, time release dependencies, and dose metric is best for expressing the EHS of nanomaterials. A major contributor to current confusion and lack of regulatory consistency is the arbitrary definition of nanomaterials being anything with a dimension between 1 and 100 nm; some definitions require between 0.15 to 50% of the particles in a sample to be in this range. As an Army-specific example, detonation of nanoenergetic material is reported to result in sintered, micron-sized bulk materials that are no longer in the arbitrary 1-100 nm "nano" size range. In this context, nanomaterials encompass a huge diversity of chemically and structurally diverse materials that make an inappropriate and cumbersome management unit; this is somewhat synonymous to enforcing a single regulatory category for "metals", which range from relatively inert (e.g., calcium) to very toxic (mercury). In addition, the EHS risk of certain carbon based nanomaterial applications may be most relatable to the leaching of dissolved metal catalysts. While existing regulations are still relevant in such cases, there is no logical need to regulate the technology without independent verification that the included materials have retained their nano—scale properties in the final product or application. While the scientific and regulatory communities are struggling with these issues, there is a lack clear guidance, databases, and tools that are needed to make risk-informed decisions and meet regulatory compliance.

To understand the potential implications of nanomaterial releases from products of interest, NanoExpert, a suite of desktop tools have been developed to calculate an estimated exposure to materials of interest to support exposure and hazard assessment for a variety of nanomaterials. The US Army ERDC's NanoExpert tool suite has been developed and is available online at: http://el.erdc.usace.army.mil/nano/ Other research groups have developed similar tools such as the Nano Product Hazard and Exposure Assessment Tool (NanoPHEAT), which represents a custom application built to draw upon the CEINT Nano Informatics Knowledge Commons (NIKC), the database system built to integrate and manage a wide range of nanomaterial data.

The release of nanomaterials from more complex matrices, such as polymers and thermoplastics among other materials has been investigated by ERDC and toxicity tests performed with the goal of developing data to determine the difference in relative biological effects between nanoparticles as ingredients and nanoparticles incorporated in a technology. Though some nanomaterials could indeed be detected in the aged samples, none of them produced discernible toxic effects with the exception of previously known effects from ionic silver impacts. This indicates that though some overall exposure to the nanomaterials in the products was possible based on the releases, the difference in toxicity, was negligible.

There are several models, such as the NanoExpert tool suite, being developed to estimate the potential impacts of nanomaterials released from products containing nanomaterials. By considering the mass of nanoparticles released during aging or abrasion, exposure models can link information on nanomaterial content in products to a range of potential impacts observed in the literature using pristine materials. Toxicity data spanning a large number of endpoints for nanoparticles such as nanoAg and carbon nanotubes have been compiled and fit to dose-response curves to serve as the comparative basis for estimating the impact of realistically estimated effective doses resulting from nanoparticulate releases from products containing nanomaterials. Figure 1 below depicts the relationships of the technology categories as drawn from across the nanomaterial literature to the releases/potential for exposure of nanomaterials from products of interest.

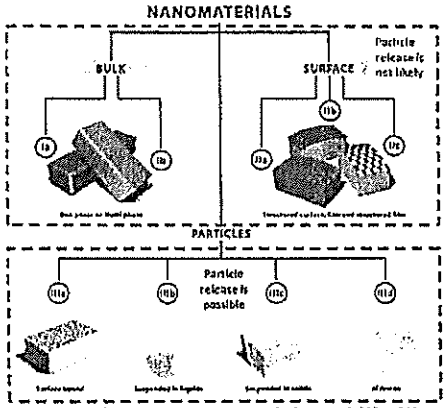

Figure 1. Categorization of products containing nanomaterials and likelihood of release associated with product life cycle (adapted from Hansen, 2007)

The proposed data mining and informatics and model development requires separate scenario descriptors for multiple exposure factors along the pathway from product containing nanomaterials to nanomaterial release and impact, including the ENM content in product, the product dose in the system (requiring user knowledge of the volume of the target system), and the fraction of the nanomaterial in the technology that will be released resulting in an exposure and effect. Previous studies completed by CPSC and partners have shown that specific nano-Ag and CNT materials did not result in an effect. However the proposed tool would be adaptable to new nanomaterial-containing products, updated information on material release (factors), and new toxicity endpoints. Because the availability and relevance of data on toxicity and, in particular, exposure scenarios for nanomaterials are newly emerging and rapidly changing, the proposed tool is designed to work with varying levels of information. Existing toxicity data can be tapped for insight on expected responses based on a series of exposure assumptions or based on specific scenario data; moreover, data gathered on exposure scenarios and material release will support not only improved risk estimates, but also investigations of bioavailability, effective dose, and ultimate response.

The ERDC will manage the proposed work and develop collaborations as needed to complete the work identified in the interagency agreement. The proposed budget is a total of $720,000 composed of two options. Option 1 ($500,000) includes the data

curation and visualization tool development, toxicity data development, and characterization of materials. Data curation must include:

- gathering and evaluating the current state of nanomaterial toxicity data
- consolidating the data gathered in a form that is useful for further research, and
- presenting the curated data in a form that permits curated data to be used for additional nanomaterial toxicity research by the parties to this Interagency Agreement and others in the nanomaterial community.

Option 2 ($220,000) includes model development including transformation of nanomaterials as well as further development of a prioritization tool. Further details of the budget are outlined in Table 1 below.

4. AUTHORITY

The authorities for this agreement are:

(A) ERDC Authority: Economy in Government Act (31 U.S.C. 1535).

(B) CPSC Authority: Section 27(g) of the Consumer Product Safety Act, (15 U.S.C. 2076(g)) and Section 5(c) of the Consumer Product Safety Act (15 U.S.C. 2054(c)).

5. CPSC FURNISHED MATERIALS/EQUIPMENT

CPSC staff will provide the list of nanomaterials to be included in the data curation, and tested in the toxicity studies.

5. CONFIDENTIALITY REQUIREMENTS AND DATA SHARING

ERDC agrees to the following terms and also agrees to include these requirements as mandatory terms and conditions to any subcontract or award made pursuant to this IAG.

A. To the extent permitted by law, all information reported to or otherwise obtained by CPSC or its agents under the Consumer Product Safety Act (CPSA) and provided to or shared with ERDC and any subcontractor or awardee, which contains or relates to a trade secret or other matter referred to in section 1905 of title 18, United States Code, or subject to section 552(b)(4) of the title 5, United States Code, shall be held in confidence by ERDC and the subcontractor or awardee's personnel.

B. To the extent permitted by law, including the Freedom of Information Act, ERDC and any subcontractor or awardee agree not to release the identity of any manufacturer of any product being tested or reviewed in conjunction with this IAG. These provisions are consistent with and do not supersede, conflict with, or

otherwise alter the employee obligations, rights, or liabilities created by existing statute or Executive order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General of a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights, sanctions, and liabilities created by controlling Executive Orders and statutory provisions are incorporated into this agreement and are controlling.

C. All documents and other materials developed pursuant to this IAG shall have appropriate statements to indicate that the work was performed pursuant to the IAG by CPSC; that the documents and other materials produced are the views of the staff or members (present or past) of CPSC; and that although the documents and other materials may have been developed in conjunction with CPSC staff, the documents and other materials do not necessarily represent the views of the Consumer Product Safety Commission.

Any publications of or publicity pertaining to the work performed under this Agreement shall include the following:

"This project was funded by CPSC. The content of this publication does not necessarily reflect the views of the Commission, nor does mention of trade names, commercial products, or organizations imply endorsement by the Commission."

D. ERDC and any subcontractor or awardee must submit any report, manuscript or other document containing the results of work performed under this agreement to CPSC before such document is published or otherwise disclosed to the public in order to ensure compliance with Section 6(b) of the Consumer Product Safety Act (15 U.S.C. 2055(b)), CPSC Regulations (16 C.F.R. Part 1101), and CPSC Directives (Order No. 1450.2).

Prior submission allows the CPSC staff to ensure compliance with applicable disclosure provisions. The awardee's researchers agree to consult with any drafts of reports or presentation materials to CPSC staff for review. CPSC staff will endeavor to review and return such materials within 20 business days.

The clearance requirements restrict disclosure of information that:

1. permits the public to identify particular consumer products; and
2. reflects on the safety of a class of consumer products.

E. ERDC and any subcontractor or awardee shall insure that the rights to all information, uses, processes, patents, and other developments resulting from the

cooperative agreement activity will be made available to the public without charge on a nonexclusive basis.

6. TERMS AND CONDITIONS

A. CPSC will transfer $720,000 to ERDC as reimbursement for conduct of the proposed research by ERDC and any subcontractor or awardee conducting research pursuant to this IAG.

B. Work to be undertaken and deliverables to be provided:

Proposed Tasks

Task 1. Data curation, data modeling, and graphical interface development. The proposed effort will further develop the models used to assess risk of products containing nanomaterials by 1) increasing literature curation, 2) performing relevant toxicity testing to improve the robustness of the current model's ability to provide consumer hazard assessment and protection guidance, and to illuminate data gaps in toxicity and exposure data for future investment.

Task 1.1. Data Curation.

Exposure and effect models require a data set to support accurate predictions of potential risk of products containing nanomaterials. There are currently several activities at ERDC and other research organizations to build databases that can support models. In this activity literature will be reviewed to support probabilistic models and visualization tools. The data curation efforts will focus on toxicity data for a suite of nanoparticles including nano-Ag, CNTs, and nano-Ti. The data curation will include both ecological (plant and animal) as well a mammalian species, incorporate multiple routes of exposure, and consider multiple toxicity endpoints. The development of these databases will be coordinated with other organizations building databases as discussed through the NKI (NNI) initiative.

Task 1.2. Model Development.

An SSD is a statistical distribution that captures the variation in toxicological sensitivity among a given set of species to a certain chemical or nanoparticle. The SSD is expressed as a cumulative distribution function (CDF) composed of specific effect–concentration metrics (e.g., LC50, EC50, LOEC, or NOEC values) obtained from toxicity studies on the x axis and the cumulative proportions of affected species (p) on the y axis (Posthuma et al. 2002). Benchmarks or criteria can be derived from an SSD by selecting a percentile (p) to protect 1 p percent of species on the y axis and reading off the corresponding concentration on the x axis as dictated by the SSD. Therefore, instead of selecting a single-point benchmark from residue data reported in a single study, a risk manager can use the SSD to select a residue-based effect benchmark that corresponds to a given level of desired protectiveness (e.g., protection of 95% of population).

As part of the model development, we will generate a cumulative distribution frequency for the nanoparticles of interest to CPSC. The CFD will rely on the data availability in Task 1.2 and rely on other databases where appropriate. The goal is to develop CDF for multiple endpoints and routes of exposure.

Task 1.3. Development of a Graphical User Interface.

Data and models will be visualized through the development of a graphical user interface and visualization tool. The US Army ERDC has developed a prototype of the tool, NanoExpert, Figure 2) that will be developed as part of this effort.

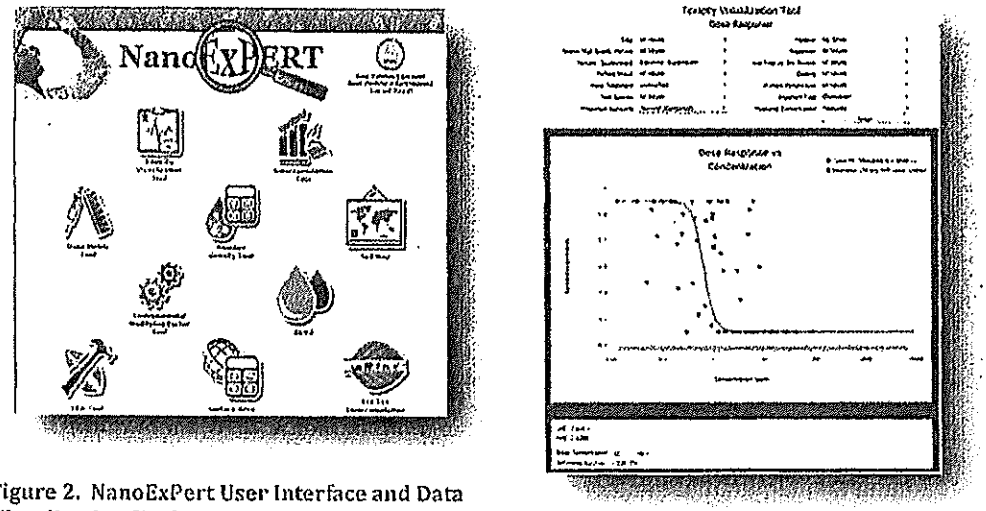

Figure 2. NanoExPert User Interface and Data Visualization Tool

Data will be presented in an endpoint sensitivity distribution graphical interface that will facilitate selection on the part of the user of the endpoint that is relevant for their considerations (e.g. protection level of interest). For each endpoint, a dose-response curve will be accessible; the model then forecasts a projected point on this dose-response curve for the exposure scenario represented by the model input assumptions. An effort will be made to include curated data on low and no effect doses so that benchmark indicators (e.g. NOELs) can be placed over the literature-derived dose-response curves for a reference when adding the superimposed "effective dose" of the user-defined exposure scenario onto the curve.

Task 2. Development of Product Relevant Exposure and Toxicity Data.

The CPSC has specific classes of technologies or products containing nanomaterials that are of interest. These materials and products include polymers containing nanoparticles but might also include others currently in development by Department of Army that would be good model compounds. These might include particles in diffuse coatings such as CNT in paint or nanoAg on textiles or printed devices. Another class of products includes the durable coatings or solid matrix such as a 3D printed thermoplastic

containing carbon nanotubes. The studies in this task will be coordinated with CPSC to identify the best candidate for the studies. Ultimately these data will address the gaps identified in the data curation, modeling and visualization described in Task 1.

Task 2.1. Product Aging and Release.

Particle release studies will focus on the release of particles from the composite material. The goal of these studies is to couple analytical approaches to quantify the release and form of particles from the composite material with toxicity metrics. This effort will be conducted in collaboration with CPSC and CPSC collaborators. Briefly, Plastics enabled with the three classes of materials selected for this work will be aged in accordance with the NIST methods of generating abraded materials that were employed in prior research conducted for CPSC by Duke University Center for CEINT. These abraded materials will subsequently be characterized in Task 2.2 and submitted to toxicity assays in task 3.

Task 2.2. Characterization of Nanoparticles.

Characterization of pristine and aged products containing nanomaterials will be performed on nanomaterials in pristine form, as well as in the form of abraded materials from products containing nanomaterials. The release of CNT from the composite will require the application of a suite of spectroscopic and microscopic analyses to determine the potential changes of CNT with weathering of products. These techniques involve:

- Scanning electron microscopy (SEM): FEI Nova NanoSEM 630 that is capable of high-resolution imaging on non-conductive materials
- Atomic force microscopy (AFM) using a Bruker (Veeco) Nanoscope V: investigate nano- and micron-scale changes in the CNT composite surface and CNT aggregates in the centrifugation pellet
- Solid-state ^{13}C-NMR (cross- and direct-polarization techniques) and/or near-edge x-ray absorption spectroscopy (NEXAFS): determine changes in carbon, nitrogen, and oxygen speciation due to weathering

Other analytical techniques that will be considered include:

- A Postnova Analytics (Salt Lake City, UT) F-1000 symmetrical flow field flow fractionation system comprising a 1 kDa regenerated cellulose membrane and interfaced with a PerkinElmer Elan DRC II inductively coupled plasma mass spectrometer.
- Shimadzu 800 HS energy-dispersive x-ray (EDX) fluorescence spectrometer to determine trace-metal/bulk elemental content w. Suspensions will be analyzed under a non-desiccating helium atmosphere.
- Aggregate characterization of particles released in the aqueous phase:
    - *Size and shape:* Particle dimensionality will be determined via dynamic light scattering (DLS) using a Malvern Zetasizer or Brookhaven 90Plus. Aggregates will be characterized based on their time-integrated scattering profiles. Particle shape will be estimated using the semi-static light scattering (SLS) functionality on the DLS by constructing a Debye plot based on the concentration-dependent scattering intensities at forward- (90 deg) and back-

scattering (175 deg) angles, respectively. Based on the estimated aggregate geometry, aggregate size will be calculated from the intensity-weighted average of the scattering profile.

- *Aggregate. charge:* The pH-dependent surface charge profile will be determined through potentiometric titration of the CNT dispersion using the MPT autotitrator, which is connected to the Malvern system via a flow cell. Particle size and zeta potential will be measured using a pre-programmed equivalence points along the titration. Titration data will be modeled using surface complexation modeling to determine the charge speciation of the aggregates, and calculate the zero point of charge.

Task 3. Toxicity Studies on Products Containing Nanomaterials.

Additional product-specific toxicity assays are proposed to expand beyond the initial dataset, particularly when there are data gaps. Starting with existing exposure data, ERDC and any ERDC subcontractor or awardee shall identify gaps for aging and toxicity testing. Assessing the toxicity of individual contaminants can be conducted using existing information and models. However, where there are mixtures, such as during the aging and release of nanoparticles from a product or technology there are likely to be other constituents such as the matrix or dissolved ions. Bioassays can be employed to determine the relative toxicity of an individual constituent and a matrix bound particle in a fragment of the product to determine its relative toxicity.

In this study ERDC and any ERDC subcontractor or awardee proposes to use bioassays to collect additional data where needed. A suite of potential bioassays including the zebrafish (often used as a mammalian model), medaka, daphnid, or other non-traditional test organism may be used. In some cases it is more relevant to use a cell-based assay to focus on specific mechanisms of exposure. Toxicity through inhalation exposure can be assessed using cytotoxicity assays using lung cells. In this study, ERDC and an other ERDC subcontractor or awardee proposes particle toxicity to lung cells be examined using a co-culture of type II pneumocytes (A549, cells that produce lung surfactant) and alveolar macrophages (U937, resident lung macrophages). This combined culture offers the benefit of capturing biological effects on the alveolar cells and also effects mediated through inflammation induced by the macrophages.

The bioassays used for these studies will be selected based on the products/nanomaterials evaluated, relevance to the anticipated exposure route, gaps in the database, and relevance to the CPSC. Data will be from these studies incorporated into the model and will support Tasks 1 and 2 including determination response factors/relationships and other related deliverables.

Task 4. Nanotechnology Prioritization Tool

In 2013, the CPSC and ERDC signed an agreement to develop a tool to rank products containing nanomaterials based on a number of predetermined criteria including the toxicity potential of the nanomaterial, the potential exposure to consumers, and use

potential of the product. The prototypical model was developed and tested by CPSC, but it was noted that the release of nanomaterials from complex matrices, composed for example of thermoplastics or polyurethane foams, is important for assessing exposure and risk of nano-enable products and is not integrated in the model developed by ERDC. This task will develop model further to develop and integrate databases developed in the project. The data curation efforts will be used to support the toxicity information used in the prioritization model.

Task 5. Perform gap analysis in database; develop final report

Based on the results of the project, ERDC and any ERDC subcontractor or awardee will develop a report noting where the existing toxicity and exposure data leave gaps that impede the ability to deliver conclusive guidance, in order to inform future decisions on toxicity and exposure testing needs and associated data curation investments.

Budget: The following table provides the above-listed tasks and their associated budgets.

	Task and Activity	Subtotal
1	Data Curation and Modeling	
1.1	Data curation	$125,000
1.2	Model development	$75,000
1.3	*Graphical user interface and visualization tool*	$75,000
	Subtotal	$275,000
2	Development of Exposure and Toxicity Data	
2.1	Product aging and release	$75,000
2.2	Characterization of nanoparticles	$75,000
	Subtotal	$150,000
3	Toxicity Studies on Products Containing Nanomaterials	$100,000
4	Nanotechnology Prioritization Tool	$120,000
5	Reporting	$75,000
Total funding		$720,000

7. REPORTING REQUIREMENTS

The ERDC will provide to CPSC an interim report documenting the toxicity testing protocols, risk modeling tools and the resulting data at the completion of each task. An interim report will also be completed at the end of each fiscal year. The deliverables for this agreement are 1) a database of toxicity information for selected nanomaterials, 2) a model that predicts matrix effects on toxicity potential and potency, and 3) an updated nanomaterial prioritization tool.

8. ACCOUNTING DATA

The transfer of funds shall be from CPSC to DOD (ACE) through the On-Line Payment
Collection (OPAC) system using the following accounting data:

Transfer From: CPSC BETC: DISB Taxpayer ID Number (TIN): 520978750
Agency Location Code (ALC): 61-00-0001 DUNS: 069287522
US Treasury Code: 61150100 AMOUNT: $720,000.00
ACCOUNTING DATA: 0100A15DSE 2015 2370400000 EXHR004000 255A0

To: ERDC
ALC: 000-8736
DUNS:098165889
Account info: 099990
Treasury Code: 96X3123

11. DURATION OF AGREEMENT AND AMENDMENTS

This agreement will become effective when signed by the parties. The agreement will expire on 12/16/16 but may be amended at any time by mutual written consent of the parties.

12. DISAGREEMENTS

In the event that CPSC and ERDC have a disagreement arising under this interagency agreement, the parties shall cooperatively seek to resolve the disagreement by themselves. If the disagreement cannot be resolved between them, the parties agree to seek the assistance of a third party in resolving the disagreement.

13. CONTACTS

The contacts of each party to this agreement are:

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The parties agree that if there is a change regarding the information in this section, the party making the change will notify the other party in writing of such change.

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Date: 9/1/15