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April 6, 2011

James Alwood
Chemical Control Division
US Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Room 4133J, Mail Code 7405M
Washington, DC 20460

RE: NanoSafety Consortium for Carbon -- Proposed
Testing Agreement

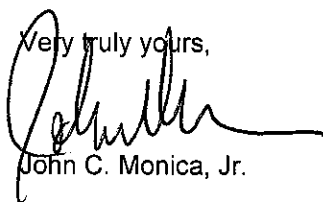
Dear Jim:

Enclosed please find a proposed testing agreement proffered to EPA by several members of the NanoSafety Consortium for Carbon under Section 4 of the Toxic Substances Control Act. We respectfully ask EPA to expeditiously consider our proposal and initiate the public comment and negotiation process set forth under 40 C.F.R. § 790.22, et seq. at your earliest possible convenience.

We believe the joint approach to toxicity testing for nanoscale carbon materials outlined in our proposed agreement presents EPA, our members, and the public with a unique opportunity to address fundamental environmental, health, and safety issues not afforded by a traditional company-by-company, material-by-material approach. Additionally, our scientific advisory board and external liaisons are excited about engaging EPA regarding the technical details of the proposed testing regime.

Please feel free to call or email if you have any questions. We look forward to working with you and others at EPA on this proposal.

Very truly yours,



John C. Monica, Jr.

JCM:alm

cc: J. Willis, Director, Chemical Control Division

WASHINGTON/179168v.1



NanoSafety Consortium
FOR CARBON

TERMS OF PROPOSED TESTING CONSENT AGREEMENT – APRIL 2011

Pursuant to Section 4 of the Toxic Substance Control Act (TSCA), the below-listed members of the NanoSafety Consortium for Carbon (NCC) respectfully submit terms for a proposed testing consent agreement to the United States Environmental Protection Agency (EPA) in accordance with the requirements of 40 C.F.R. § 790.22, et seq. and the procedures set forth therein.

The effective date of the testing agreement shall be the final date upon which it is signed by EPA and all signatories. The definitions appearing in 40 C.F.R. § 790.3 are hereby incorporated by reference.

A. Testing Sponsor

The principal test sponsor is the NanoSafety Consortium for Carbon, c/o Richard C. Pleus Ph.D., Intertox Inc., 600 Stewart St., Suite 1101, Seattle, WA 98101, (206) 443-2115, rcpleus@intertox.com. Sponsors of individual tests are set forth in Section D below. NCC's legal counsel is John C. Monica, Jr., Porter Wright Morris & Arthur LLP, 1919 Pennsylvania Ave., N.W., Suite 500, Washington, DC 20006-3434, (202) 778-3050, jmonica@porterwright.com. Actual testing will be undertaken by independent third-parties approved by EPA.

B. Substances to be Tested

The chemical substances to be tested may include representative (i) purified **multi-walled carbon nanotubes** ranging from 4 to 600 nanometers in diameter and less than 30 micrometers in length; (ii) purified **double-walled carbon nanotubes** ranging from 1.5 to 4 nanometers in diameter and less than 5 micrometers in length; (iii) purified **single-walled carbon nanotubes** ranging from .7 to 2 nanometers in diameter and less than 30 micrometers in length; and (iv) purified **graphene nanoplatelets** in flake/sheet form ranging from .5 nanometers to 100 nanometers thick. All test materials will be purified by the National Institute of Standards and Technology to be at least 99 percent pure. Final test materials will be approved by the EPA and will be selected to adequately represent the constituency of the final signatories to the testing agreement.

C. Testing

1. The characteristic for which testing will be conducted is subchronic inhalation toxicity in rodents, or such other toxicity testing as may be approved by EPA to achieve the intent and purpose of the testing agreement. As appropriate, consideration will be given to using *in vivo* instillation rather than inhalation test methods. Test data will be developed under standards based on TSCA test guidelines in 40 CFR parts 796, 797, and 798, Organization for Economic Cooperation and Development (OECD) test guidelines, or other suitable test methodologies.

Specifically, the signatories will conduct a 90 day inhalation toxicity study in rats with a post exposure observation period of up to 3 months, including broncholaveolar lavage fluid analysis (OPPTS 870.3465 or OECD 413), or such other testing as may be approved by the EPA to achieve the intent and purpose of the testing agreement. Testing guidelines will be modified to account for nanoscale properties of the materials being tested. Such modifications are subject to EPA approval and will be incorporated into the below-referenced study plan.

2. All testing will be conducted in accordance with EPA Good Laboratory Practice regulations (40 C.F.R. § 792), and may be coordinated with the Department of Health and Human Services' National Toxicology Program.

3. Prior to testing, the signatories will submit a detailed study plan in accordance with the requirements of 40 C.F.R. § 790.62 for EPA's review, modification, and approval.

D. Division of Testing Responsibilities

The below-listed signatories will undertake responsibility for the testing the indicated materials only:

Multi-walled Carbon Nanotubes: Continental Carbon Nanotechnologies, Inc.; Cheap Tubes, Inc.; NanoLab; Nanoshel; SouthWest NanoTechnologies, Inc.

Double-walled Carbon Nanotubes: Cheap Tubes, Inc.; Continental Carbon Nanotechnologies, Inc.; NanoLab

Single-walled Carbon Nanotubes: Applied Sciences; Cheap Tubes, Inc.; Continental Carbon Nanotechnologies, Inc.; Nano-C; NanoLab; Nanoshel; Pyrograf Products; SouthWest NanoTechnologies, Inc.

Graphene Nanoplatelets: Angstrom Materials, LLC; Cheap Tubes, Inc.; XG Sciences, Inc.

E. Testing Deadlines

All testing under the study plan contemplated in Paragraph C(3) above will be completed at least 14 weeks before either of the following circumstances (a) manufacturing or importing a total of [tbd] kg of the chemical substance in the respective nanoscale material category by the responsible party/group, or (b) the expiration of [tbd] years [tbd] months after the commencement of non-exempt commercial manufacture of the chemical substance in the respective nanoscale material category, whichever comes first. The production/time limit shall be calculated from a date two years after the effective date of the testing agreement.

F. Reporting and Dissemination of Testing Data

Interim progress reports will be submitted to EPA at 60 day intervals beginning on the effective date of the testing agreement. A final report will be submitted to EPA within 120 days after conclusion of testing. Testing of each chemical substance will be completed within two years after initiation of said test. Testing results will be announced to the public in accordance with the

procedures specified in Section 4(d) of TSCA and the disclosure of data generated by such testing will be governed by Section 14(b) of TSCA.

G. Export Notification

The signatories will comply with the notification requirements of Section 12(b)(1) of TSCA and part 707 of 40 C.F.R. § 790 if they export or intend to export the chemical substances or mixtures identified in Paragraph B above or any other chemical substance or mixture covered by the testing agreement. Any other person who exports or intends to export such substances or mixtures will be subject to the same export notification requirements.

H. Significant New Use Rule

In the event EPA promulgates a significant new use rule under Section 5(a)(2) of TSCA which is applicable to the chemical substances or mixtures identified in Paragraph B above, the testing agreement will have the status of a test rule for purposes Section 5(b)(1)(A) of TSCA and the final signatories to the testing agreement will comply with the data submission requirements imposed by that provision.

I. Violations

The signatories agree that for each product grouping contemplated under Section D above, a violation of the testing agreement's provisions concerning that product grouping will constitute a "prohibited act" under Section 15(1) of TSCA and will trigger all provisions of TSCA applicable to a violation of Section 15 as to the parties responsible for the testing applicable to that product grouping.

J. Severability

In the event one or more provisions of the testing agreement are determined to be unenforceable by a court, the remainder of the testing agreement will not be presumed to be valid, and EPA will then either initiate a rulemaking proceeding or publish in the Federal Register the Administrator's reason for not initiating such a proceeding.

K. Inspections

EPA may conduct laboratory inspections and/or study audits of the testing being conducted pursuant to the testing agreement in accordance with the authority and procedures contained in Section 11 of TSCA.

L. Final Agency Action

EPA's acceptance of the testing agreement constitutes "final agency action" for purposes of 5 U.S.C. 704.

M. Other Requirements

Other requirements that the parties agree are necessary to achieve the purposes of TSCA are as follows:

- (i) testing under the testing agreement will satisfy all TSCA toxicity testing requirements for all of the signatories' nanoscale carbon products as of the effective date of the testing agreement;
- (ii) EPA will allow the signatories a reasonable range of modification **[tbd]** of their existing nanoscale carbon products without requiring renewed toxicity testing;
- (iii) Upon written election by any signatory, any testing completed under the testing agreement will replace and satisfy the toxicity testing requirements in any signatory's Section 5 TSCA consent order;
- (iv) EPA will suspend the TSCA toxicity testing requirements in any signatory's Section 5 TSCA consent order while the testing contemplated by the testing agreement is ongoing;
- (v) Materials characterization of substances to be tested under the testing agreement will be based on OECD and/or ISO criteria and will be conducted by the U.S. Army Engineer Research and Development Center; and
- (vi) Workplace assessments of signatories' facilities will be conducted in coordination with National Institute for Occupational Safety and Health based on their good nanomanufacturing guidelines and other published documents

NCC Members Requesting EPA's consideration of the Terms of this Proposed Testing Agreement:

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