

## **EPA Working on Test Rule for Multi-Wall Carbon Nanotubes/TSCA Section 8(a) Rule for Several Nanoscale Substances**

**By Lynn L. Bergeson**

As you may know, twice each year the U.S. Environmental Protection Agency (EPA) publishes a detailed listing of all matters on which it is working. The document is referred to as the Semiannual Regulatory Agenda, and is published each spring and fall. The most recent spring issue was published on May 11, 2009.

The Regulatory Agenda is intended to update the public on regulations and major policies currently under development, review existing regulations and major policies, and identify rules and major policy makings completed or canceled since the last Agenda. While the timeframes noted in the Agenda are often off, sometimes significantly so, the document is a useful resource in terms of cataloging ongoing initiatives and having them conveniently placed in a single document. A careful review will also yield important information that sometimes is not widely publicized in other contexts.

One such notice appears in the May 11, 2009, Semiannual Regulatory Agenda. In it, EPA notes that it is preparing a Toxic Substances Control Act (TSCA) Section 4 test rule on multi-wall carbon nanotubes. EPA has made many references to its inclination to issue a Section 4 test rule, but the notice in the Regulatory Agenda is a clear signal that EPA is one step closer to issuing a proposed TSCA Section 4 test rule.

### **TSCA Section 4 Test Rules**

A TSCA Section 4 test rule identifies data and other information EPA is authorized to compel from chemical substance manufacturers and importers, and occasionally also from processors, of the chemical of interest. In this case, and according to the notice, the test rule would seek certain data and information on multi-wall carbon nanotubes. Typically, Section 4 test rules seek toxicological data of one form or another. Because such data can be costly and time consuming to generate, Section 4 test rules are typically unwelcomed news to those entities who are required to comply with them.

Others, however, see a potential competitive advantage in EPA's compelling data production from all entities included within a class of business interests. In this case, that would include all producers and importers of multi-wall carbon nanotubes. The trick is, of course, to ensure that all manufacturing entities within a class are compelled to comply with the rule to ensure that there are no free riders (entities within the class who escape having to comply with the rule and thus avoid expense). Over TSCA's long history, industry and EPA have struggled with how best to ensure all entities within a class are subject to a TSCA Section 4 test rule in a way that averts the free rider effect. Although no Section 4 test rule is likely to be perfect in this regard, to many, a mandatory TSCA test rule may be more palatable than the alternative, namely an enforceable consent agreement (ECA). An ECA binds only those entities that are signatories to the terms of the agreement that spells out what data and information are required to be produced and by when.

The Semiannual Regulatory Agenda unfortunately does not offer much specific information with regard to what EPA may have in mind. The notice specifically provides:

A TSCA Section 4(a) test rule may be needed to determine the health effects of multiwall carbon nanotubes. The results of the tests that could be required under this rule could assist EPA in understanding the health effects of the substance to manage/minimize any potential risk and exposure. Results could also help with establishing a correlation between the chemical/physical properties and health effects needed to protect the health of workers handling the substance.

### **TSCA Section 8(a)**

Although not noted in the Regulatory Agenda, EPA is also planning to issue a TSCA Section 8(a) rule. Under TSCA Section 8(a), EPA may require, by rulemaking, that manufacturers and processors of chemical substances maintain records and/or report such data as EPA may reasonably require to carry out the TSCA mandates. EPA expressed its interest in issuing a TSCA Section 8(a) rule in the Nanoscale Materials Stewardship Program (NMSP) Interim Report, which is available at <http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf>. EPA stated that it would consider how best to address data gaps on existing chemical nanomaterial production, uses, and exposures. While it is not clear when any TSCA Section 8(a) rule may be issued, it likely will be sometime this year.

NanoBusiness Alliance members, especially multi-wall carbon nanotube manufacturers and importers are urged to monitor the *Federal Register* for both rules. Members may wish to consider consulting with TSCA experts to develop appropriate strategies now to anticipate and address the consequences of the issuance of a test rule along these lines.

To receive an e-mail with a link to the new Semiannual Regulatory Agenda, send an e-mail message with your name and address to: [nscep@bps-lmit.com](mailto:nscep@bps-lmit.com) and put E-regulatory Agenda: Electronic Copy in the subject line. To receive information on the NMSP, complete the form available at <http://www.epa.gov/oppt/nano/nano-contact.htm> and request to be added to the NMSP e-mail list.

Lynn L. Bergeson is Managing Director of Bergeson & Campbell, P.C., a Washington, D.C. law firm focusing on conventional and engineered nanoscale chemical, pesticide, and other specialty chemical product approval and regulation, environmental health and safety law, chemical product litigation, and associated business issues, and President of The Acta Group, L.L.C. and The Acta Group EU, Ltd with offices in Washington, D.C. and Manchester, UK.

74 Fed. Reg. 21992 (May 11, 2009); see also <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=200904&RIN=2070-AJ47>.