

BERGESON & CAMPBELL P.C.

Nanomanufacturing Summit 2013

State of the Union: Nanotechnology Environmental Health Safety

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Key Regulatory Issues

- Toxic Substances Control Act (TSCA) broadly regulates chemical substances
- U.S. Environmental Protection Agency (EPA) Comprehensive Environmental Assessments (CEA)
- EPA Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulation of nanosilver
- Occupational Safety and Health Administration (OSHA)/National Institute for Occupational Safety and Health (NIOSH) initiatives are also of growing significance
- Consumer Product Safety Commission (CPSC) developments

TSCA Regulatory Developments

- On February 25, 2013, EPA published a proposed Significant New Use Rule (SNUR) for 37 chemical substances that were the subject of premanufacture notices (PMN), including 12 PMN substances subject to a TSCA Section 5(e) Consent Order whose reported chemical names include the term “carbon nanofibers” (CNF)
- The PMNs state that the uses of the multi-walled carbon nanofibers (generic) will be as electrical and thermal conductivity additives, mechanical reinforcement additives, energy storage additives (battery electrodes), and chemical intermediates (these are disclosed applications, others may be non-disclosed)

TSCA Regulatory Developments (cont'd)

- The SNUR would designate as a “significant new use” the absence of the following protective measures included in the Consent Order:
 - Requires use of personal protective equipment (PPE), including impervious gloves and protective clothing (when there is a potential dermal exposure) and a NIOSH-certified air-purifying, tightfitting full-face respirator equipped with N100 filters with an assigned protection factor (APF) of at least 50 (when there is potential inhalation exposure)
 - Restricts use of the PMN substances to use only as electrical and thermal conductivity additives, mechanical reinforcement additives, energy storage additives, and chemical intermediates as specified in the Consent Order
 - Restricts processing and use of the PMN substances to industrial settings
 - Prohibits release of the PMN substances into U.S. waters during processing and use activities

EPA -- Comprehensive Environmental Assessments

- EPA is developing case documents to structure systematically available information pertaining to the product life cycle, environmental transport and fate, exposure-dose in receptors, and impacts in these receptors for particular nanomaterials in specific applications
 - Two case studies concern nanoscale titanium dioxide -- one examines its use for water treatment in the removal of arsenic and the other looks at its use as an ingredient in topical sunscreens
 - A draft case study on nanoscale silver in disinfectant sprays is also available
 - EPA released on September 30, 2013, a case study on multi-walled carbon nanotubes (MWCNT) in flame-retardant coatings applied to upholstery textiles, which builds on previous case studies by incorporating a comparative aspect with a non-nanoenabled flame-retardant material

United States -- EPA

- EPA's 2013 Regulatory Agenda
 - EPA is developing a SNUR under Toxic Substances Control Act (TSCA) Section 5(a)(2) for nanoscale materials, as well as a TSCA Section 8(a) rule to require reporting and recordkeeping
 - EPA is reportedly working on a new approach to regulating nanoscale forms of existing substances as its stated prior approach met with significant resistance

Nano Pesticides

- Nanosilver: HeiQ and NanoSilva (both are composite or hybrid particles where the silver is embedded (HeiQ) or attached to a larger silicon dioxide particle)
- On December 1, 2011, EPA announced a conditional registration for HeiQ AGS-20, a nanosilver-based product for use as a preservative for textiles
- As a condition of registration, EPA is requiring the registrant, HeiQ, to conduct a number of studies within four years
- On January 26, 2012, the Natural Resources Defense Council (NRDC) filed a lawsuit challenging the conditional registration
- Specifically, NRDC urges the court to set aside the authorization until the data EPA has requested are generated, submitted, and reviewed

Nano Pesticides (cont'd)

- Oral arguments were held on January 16, 2013
- On August 7, 2013, the court ordered the parties to submit supplemental briefs addressing EPA's conclusion that there is no risk concern for toddlers exposed to HeiQ AGS-20-treated textiles
- On August 27, 2013, EPA proposed to register Nanosilva, a nanosilver-containing antimicrobial pesticide product "used as a non-food-contact preservative to protect plastics and textiles (e.g., in household items, electronics, sports gear, hospital equipment, bathroom fixtures and accessories) from odor and stain causing bacteria, fungi, mold and mildew"
- Using robust toxicity data on nanosilver, conservative occupational exposure assumptions, leaching data showing minimal consumer exposure to nanosilver, and maximum values for risk uncertainty factors, EPA determined that for the period of conditional registration, there is a low probability of adverse risk to human health and the environment from plastics and textiles incorporating Nanosilva

Nano Pesticides (cont'd)

- As a condition of the proposed registration, EPA is proposing to require that Nanosilva LLC conduct studies during the period of conditional registration to characterize better the nanosilver in Nanosilva
- In addition, EPA is proposing to require the following inhalation route-specific studies:
 - 90-Day Inhalation Toxicity (Rat) (OCSPP 870.3465) modified to include *in vivo* bone marrow assay and functional observational battery, motor activity, and detailed neuropathology
 - Reproduction/Developmental Toxicity Screening Test (Modified OCSPP 870.3550/OECD TG 421)

Nano Pesticides (cont'd)

- No EPA risk concern for workers who use closed-system loading when mixing and loading the Nanosilva liquid suspension, EPA is proposing to require tests to confirm the 10-fold database uncertainty factor, to reduce the uncertainties related to differences in the physical properties of the nanosilver, and because there are currently no acceptable studies on the reproductive and developmental toxicity for nanosilver
- These studies must be completed within four years after issuing the registration
- Comments were due September 6, 2013

NIOSH -- Current Intelligence Bulletin (CIB) 65

- On April 24, 2013, NIOSH released *Current Intelligence Bulletin 65: Occupational Exposure to Carbon Nanotubes and Nanofibers*
 - Reviews animal and other toxicological data relevant to assessing the potential non-malignant adverse respiratory effects of CNTs and CNFs
 - Provides a quantitative risk assessment based on animal dose-response data
 - Proposes a recommended exposure limit (REL) of 1.0 $\mu\text{g}/\text{m}^3$ of elemental carbon as a respirable mass 8-hour time-weighted average concentration
 - Describes strategies for controlling workplace exposures and implementing a medical surveillance program

NIOSH -- CIB 65 (cont'd)

- NIOSH notes that in the 2010 draft of this CIB, it indicated that “risks could occur with exposures less than $1 \mu\text{g}/\text{m}^3$ but that the analytic limit of quantification was $7 \mu\text{g}/\text{m}^3$ ”
- Based on subsequent improvements in sampling and analytic methods, NIOSH states that, in the final CIB, it is now recommending an exposure limit at the current analytical limit of quantification of $1 \mu\text{g}/\text{m}^3$

OSHA -- Fact Sheet on Working Safely with Nanomaterials

- According to the fact sheet, information and training provided to workers should include:
 - Identification of nanomaterials the employer uses and the processes in which they are used
 - Results from any exposure assessments conducted at the work site
 - Identification of engineering and administrative controls and personal protective equipment (PPE) to reduce exposure to nanomaterials
 - The use and limitations of PPE
 - Emergency measures to take in the event of a nanomaterial spill or release

OSHA -- Fact Sheet (cont'd)

- According to OSHA, because certain nanoparticles may be more hazardous than larger particles of the same substance, existing occupational exposure limits for a substance may not provide adequate protection from nanoparticles of the same substance
- OSHA recommends that worker exposure to respirable CNTs and CNFs not exceed 1.0 $\mu\text{g}/\text{m}^3$ as an 8-hour time-weighted average, based on the NIOSH proposed REL

United States -- CPSC

- EPA and CPSC Collaboration
 - In December 2012, EPA and CPSC announced a worldwide research effort to assess any potential impacts of nanomaterials on people's health and the environment
 - EPA's collaborative research with CPSC is part of a larger international effort that focuses on:
 - Identifying, characterizing, and quantifying the origins of nanomaterials
 - Studying biological processes affected by nanomaterials that could influence risk
 - Determining how nanomaterials interact with complex systems in humans and the environment
 - Involving industry to develop sustainable manufacturing processes
 - Sharing knowledge through innovative online applications that allow for rapid feedback and accelerated research progress

United States -- CPSC (cont'd)

- CPSC, in working with other federal agencies, ensures that common public health concerns are met and will use research findings to inform:
 - Protocol development to assess the potential release of nanomaterials from consumer products
 - Credible rules for consumer product testing to evaluate exposure
 - Determination of the potential public health impacts of nanomaterials used in consumer products

Minimize Business Risk

- Keep abreast of pertinent developments
 - Monitor regulatory developments
 - Monitor scientific developments
- Review commercial contracts along supply chain
- Review insurance policies
- Know your operations and be prepared to address nano issues that may arise from diverse stakeholders

Resources

- U.S. EPA --
<http://www.epa.gov/ncer/nano/questions/index.html>
- National Nanotechnology Initiative --
<http://www.nano.gov>
- American Bar Association -- Nanotechnology Program --
http://www.americanbar.org/groups/environment_energy_resources/projects_awards/nanotech.html
- Bergeson & Campbell, P.C. -- Website and Nano and Other Emerging Chemical Technologies Blog --
<http://www.lawbc.com>; <http://nanotech.lawbc.com>
- National Institute for Occupational Safety and Health --
<http://www.cdc.gov/niosh/topics/nanotech>

THANK YOU

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