



BERGESON & CAMPBELL, P.C.

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BERGESON & CAMPBELL, P.C.

Nanotechnologies Practice

This document is intended to introduce you to Bergeson & Campbell, P.C.'s (B&C) nanotechnologies practice.

Virtually all federal agencies and a growing number of state agencies are now focusing on the regulatory implications of nanotechnologies. B&C offers an experienced group of professionals with unique skills, capabilities, and strong relationships with the U.S. Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), and Food and Drug Administration (FDA) decision-makers, all of which are essential for the chemical community to navigate around the challenges and benefits posed by current uses of engineered nanoscale materials and the emerging commercialization of nanotechnologies.

B&C has made a concerted effort to be in the forefront of the science policy debate involving nanotechnologies and other emerging technologies. Lynn Bergeson has an international reputation as a lawyer at the forefront of addressing legal, regulatory, and policy implications of nanotechnology. Most recently, Ms Bergeson served on the Steering Committee of the Organization for Economic Cooperation and Development's (OECD) Conference on Potential Environmental Benefits of Nanotechnology: Fostering Safe Innovation-Led Growth, presented in Paris, France on July 15-17, 2009. Ms. Bergeson presented remarks at the plenary session and organized and moderated a panel discussion on agriculture and nanotechnology. Ms. Bergeson served on the President's Council of Advisors on Science and Technology (PCAST) Nanotechnology Technical Advisory Group (PCAST nTAG), and also served on EPA's Steering Committee for the Pollution Prevention Through Nanotechnology Conference. Ms. Bergeson served in 2004 and 2005 on the American National Standards Institute (ANSI) Nanotechnology Standards Panel (NSP) Steering Committee and is now a member of the ISO Technical Committee 229 on Nanotechnologies. Ms. Bergeson also serves as counsel to the American Chemistry Council Nanotechnology Panel, which consists of companies engaged in various applications of nanotechnologies and/or engineered nanoscale materials.

Presently, B&C counsels clients on evolving regulatory and policy matters pertinent to products of nanotechnologies, particularly with respect to the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)/Food Quality Protection Act (FQPA), and OSHA/NIOSH matters. Ms. Bergeson edited the American Bar Association Section of Environmental, Energy, and Research recently completed Nanotechnology Desk Book, scheduled for release in October 2009. B&C's ground breaking article, "Reading the Small Print" (Environmental Law Institute's *The Environmental Forum*,



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March/April 2004), “FDA Regulation of Food Packaging Produced Using Nanotechnology” (*Food Safety Magazine*, April/May 2006), “TSCA and Engineered Nanoscale Substances” (*Nanotechnology Law & Business*, March 2007), “The New Business of Nanotechnology: Exploring Commercial Opportunities and Risks” (*Environmental Claims Journal*, April 2008), and “Food and Drug Administration’s Regulation of Nanotechnology” (*BNA Daily Environment Report*, September 22, 2008) are just a few of the many articles that B&C has authored and received praise for flagging significant regulatory and policy issues pertinent to nanotechnologies and engineered nanoscale materials.

Our attorneys are well versed in the legal authorities, administrative programs, and regulatory options that EPA and other government agencies, including NIOSH, OSHA, and FDA, are now exploring to address the potential risks posed by the use of engineered nanomaterials, the commercialization of nanotechnologies, and the convergence of other emerging technologies.

Experience with other legal authorities is also needed, however, and B&C is uniquely qualified to offer these diverse skills. For example, B&C professionals have long worked with EPA’s Office of Pollution Prevention and Toxics staff on TSCA Inventory and nomenclature issues. We are now working with clients on precisely these issues and on EPA’s continuing revisions of the TSCA regulatory framework, as it relates to nanomaterials and nanostructures that consist of chemical substances. B&C professionals have also long worked with NIOSH on a wide range of issues. B&C worked extensively with NIOSH on its review of titanium dioxide (TiO₂) and, in particular, its hazard assessment of TiO₂ in pigment grade and ultra fine particle form.

B&C professionals have also actively participated in the initial efforts of several offices within FDA to assess the effect nanotechnologies may have on the data requirements for different FDA approvals and clearances. B&C co-hosted with the Office of Food Additive Safety (OFAS) a meeting to discuss whether and how nanotechnologies might impact guidances issued by OFAS regarding the chemical and toxicological data needed to support a Food Contact Notification. B&C is also monitoring how the use of nanotechnologies in drug delivery systems may affect the already complicated jurisdictional issues faced when a product contains both a drug and device component. The Office of Combination Products within FDA must sort out these issues, as well as determine the extent to which different components of FDA become involved in the review of drug delivery systems. Applying the experience learned in dealing with EPA and other agencies that have considered issues of nanotechnologies in more detail to date, B&C professionals will seek to ensure that issues of nanotechnologies are considered in their proper context by FDA, as it develops a comprehensive policy on the regulation of products produced employing nanotechnologies.



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Similarly, B&C has significant experience in counseling clients and conducting advocacy initiatives with the National Toxicology Program (NTP) and has worked for years with scientists inside and outside of NTP on science policy issues involving testing protocols, the development of analytical methods, and related topics. B&C represents many companies and trade organizations that have disputed, or are in the process of disputing, the findings of an NTP study. Our assistance in this regard has consisted of marshaling the technical resources necessary to launch a comprehensive review of the findings, drafting the advocacy documents necessary to support such an effort, and representing our clients in discussions with NTP staff. Given NTP's current research initiatives involving nanoscale materials, this experience is invaluable.

We also work closely with companies and chemical testing consortia to ensure that NTP's selection of chemicals, protocols used once a chemical has been nominated for chemical testing, and the technical conclusions and inferences drawn from the test results are presented in a fair and technically defensible way. B&C offers clients an NTP tracking system that advises clients of the status of NTP's chemical testing initiatives with respect to particular chemical compounds. This tracking system allows companies an opportunity proactively to participate in the chemical testing process. Doing so helps blunt the possibility for erroneous test results, and hence minimizes the possibility that ill-conceived conclusions will be drawn with respect to test chemicals.

B&C routinely counsels clients on a wide variety of matters under the Occupational Safety and Health Act. B&C's representations include assisting many chemical consortia in the development of American Conference of Governmental Industrial Hygienists' threshold limit values applicable to, among other chemicals, carbon disulfide, phenol, ethylene glycol, and certain nickel compounds. We have worked on the development of many permissible exposure limits and routinely offer regulatory counseling and enforcement defense services.

Fact sheets from EPA, FDA, NIOSH, NTP, the National Science and Technology Council (NSTC), and the Consumer Product Safety Commission (CPSC) are available at:

- **EPA:** http://epa.gov/ncer/nano/factsheet/nano_factsheet.pdf;
- **FDA:** <http://www.fda.gov/nanotechnology/>;
- **NIOSH:** <http://www.cdc.gov/niosh/docs/2004-175/pdfs/2004-175.pdf>;



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- **NTP:** <http://ntp.niehs.nih.gov/ntp/htdocs/liason/factsheets/nanoscaleFacts.pdf> and <http://ntp.niehs.nih.gov/files/NanoColor06SRCH.pdf>;
- **NSTC:** <http://www.wtec.org/loyola/nano/IWGN.Public.Brochure/IWGN.Nanotechnology.Brochure.pdf>;
and
- **CPSC:** <http://www.cpsc.gov/LIBRARY/CPSCNanoStatement.pdf>.

August 2009