



Porter Wright Morris & Arthur

[www.nanolawreport.com](http://www.nanolawreport.com)

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## Berkeley, California's Nanomaterials Ordinance

May 29, 2007



## **Our Interest in Berkeley's Ordinance**

- “The perils of pre-emptive regulation,” Nature Nanotechnology, Vol. 2, February 2007.
- **Peer-Review Process**
- **Nanotechnology Law Report**



## **Berkeley's Motivations**

- Perceived slowness to act by federal and state governments.
- U. Cal. Berkeley & Lawrence Nat'l Labs.
- First mover/trend setter.



# **Regulatory Structure – Two Parts**

1. Ordinance Itself.

Concise, basic requirements.

2. Disclosure Guidelines.

How to comply with ordinance and when.



## **1. Ordinance -- Operative Language**

“All facilities that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent release and mitigate such material; [...] All manufactured nanoparticles defined as a particle with one axis less than 100 nanometers in length shall be reported in the disclosure plan.”



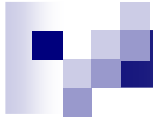
## **Six Primary Concerns With Ordinance**

- Are toxicology reporting requirements reasonable?
- Are materials handling requirements reasonable?
- Minimum threshold requirement?
- “Manufactured” nanoparticles only?
- Will labeling as “Hazardous” spawn litigation?
- Confidentiality concerns?



# **Toxicology Reporting** **Requirements?**

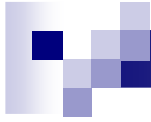
“. . .shall submit a separate written disclosure of the current toxicology of the materials reported, to the extent known...”



# **Materials Handling** **Requirements?**

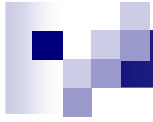
“ . . . how the facility will safely handle, monitor, contain, dispose, track inventory, prevent release and mitigate such material . . . ”





# **Minimum Threshold Requirement?**

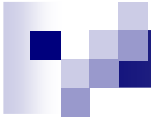
“All manufactured nanoparticles  
. . . shall be reported in the disclosure plan.”



# “Manufactured” Nanoparticles Only?



# **Will Labeling as “Hazardous” Spawn Needless Litigation?**



# **Confidentiality Concerns?**



## **2. Disclosure Guidelines**

**When? June 1, 2007.**

**What is Required?**

**A LOT MORE THAN THE  
ORDINANCE ITSELF WOULD  
LEAD YOU TO BELIEVE  
MIGHT BE REQUIRED.**



# **Disclosure Guidelines**

## **Four Categories of Information**

### **A. General Information.**

(Materials Characterization).

### **B. Toxicology.**

### **C. Occupational and Environmental Protection.**

### **D. Control Band Measures.**



## **A. General Information**

- **Common name; CAS #.**
- **Average and max. daily amount stored on site.**
- **Physicochemical props.: 11 specific areas including particle dimensions, surface area, mass, solubility, reactivity.**
- **Source of material (address & contact info.).**
- **Substrate and its toxicity.**
- **Use of material within site, intended downstream use, info. re: benefits of application.**



## **B. Toxicology**

- 1. Inhalation toxicity.**
- 2. Dermal penetration/toxicity.**
- 3. Oral toxicity.**
- 4. Mutagenicity/genotoxicity.**
- 5. Reproductive toxicity.**

**Ecological information: effects on organisms, degradation/biopersistence; bioaccumulation potential.**





## **C. Occupational and Environmental Protection**

- **Safe handling info.**
- **Potential exposure pathways and likelihood.**
- **Personal protective equipment in use.**
- **Engineering and administrative controls in place.**
- **Employee training procedures.**
- **Clean up methodology for spills and releases.**
- **Storage container(s).**
- **Site safety map indicating all of the above.**



## **D. Control Band Measures**

**Associate material with one of four control bands. List control measures in use which are commensurate with the band.**

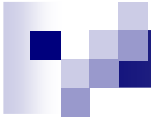
- 1. Low toxicity and no exposure pathways.**
- 2. Moderate toxicity and exposure pathways.**
- 3. High potential toxicity and exposure pathways.**
- 4. Unknown toxicity and potential exposure pathways.**



## Other

- **Possible “Trade Secret” designation under Cal. H&S 25538.**
- **“Where information is not available, please indicate this in the disclosure.”**
- **“If an exposure potential is present but insufficient toxicological information is available, a precautionary approach should be taken which assumes the material is toxic.”**

Because comprehensive toxicity data is not available across the broad range called for by Berkeley, arguably most if not all nanomaterials will be treated as "toxic" under the City's approach.



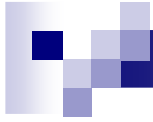
# **Pros and Cons of Approach**



# **Food for Thought**

“[N]anotechnology is likely to produce calls for entirely new forms and degrees of regulation. Such calls are likely to be justified, at least in part; but those heeding them must be aware of the twin dangers of too little regulation, and too much. Both errors present risks. In the first case, the danger takes the form of unnecessary or inappropriate rules, or worse, stagnation. In the other case, the risk is that the lack of a necessary rules or vigilance could lead to safety hazards. The choice is not a simple one between the accelerator and the brake, for the law of unintended consequences operates with a vengeance where technology is concerned.”

F. Fiedler, et al., “Legal Problems of Nanotechnology: An Overview,” 3 S. Cal. Interdisc. L. J. 593 (1994).



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