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Responding to DTSC's Data Call-In for Carbon Nanotubes –

Monitoring, Presence in the Environment, and Safety

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DTSC's CNT DCI Questions on Safety

- Three of the DTSC questions (Questions 2-4) get at what we know about safety and how we know it
  - Monitoring methods for CNT in workplace and environment
  - Knowledge of presence in the environment
  - Knowledge of safety
- How might answers affect?
  - Public perception of the effectiveness of risk management
  - Identification of "differential toxicity" across CNTs
  - Identification of regulatory risk management needs
  - Identification of data and methods needs

DTSC Question 2

What sampling, detection and measurement methods are you using to monitor (detect and measure) the presence of your chemical in the workplace and the environment? Provide a full description of all required sampling, detection, measurement, and verification methodologies. Provide full QA/QC protocol.

- How will responses to this question affect perceptions of responsible product stewardship?
- Monitoring methods are specific to risk management needs: what are the goals?
- *Proving a negative:* how to confirm low release rates relative to possible health/environmental effects?
- Start with an understanding of the physics; Use a suite of tests?
  - Dust monitoring to electron microscopy – but not Raman spectroscopy (yet)

DTSC Question 3

What is your knowledge about the current and projected presence of your chemical in the environment that results from manufacturing, distribution, use, and end-of-life disposal?

- Again – how will these responses affects perceptions of stewardship? This is an overall risk communication message for the entire industry.
- Knowledge is a weight of evidence evaluation
- Evidence about presence in the environment comes from
  - Physics of the material and its uses (what release rates are likely, from where?)
  - Generalizable knowledge from other similar materials
  - Data specific to the material
- Expectation of low release and limited movement but – again – what does it take to confirm a negative?

DTSC Question 4

What is your knowledge about the safety of your chemical in terms of occupational safety, public health, and the environment?

- A call for risk communication text or data?
- Safety has toxicity and exposure components
- Knowledge is a weight of evidence evaluation
- Evidence comes from
  - Knowledge of presence in environment and exposure (see Q2 and Q3)
  - Knowledge of protections in place (see Q5)
  - Data on toxicity - each CNT is a specific material with a specific toxicity profile
  - Generalizable information from the open literature can add to the weight of evidence, but the data combination rules for “meta-analysis” are not clear yet

Generalizable Information

- CNT dimensions affect macro structure and behavior
  - agglomeration and its persistence in key media
  - biological and environmental fate
  - “dustiness” in terms of free CNTs
- Key factors to *critical toxicity* endpoints
  - aspect ratio, rigidity, defect rate, biological fate, persistence, more?
- Matrix uses keep CNTs in place, limit their release (and their movement if released - Data?)

Data Set Is Growing – How Do We Use It?

- Public data – eg, MWCNT studies
  - A negative chronic cancer study for one type, positive "asbestos like" for another type, positive immune, inhalation toxicity, etc (about a dozen recent studies).
  - OECD testing program, METI testing program, INNO:CNT testing program?
- Private data
  - EPA PMN submissions and consent orders
    - varying numbers of supporting studies in the submissions
    - more than a dozen 90 day inhalation studies in process?
  - R&D data on physical characteristics and toxicity?

Risk Communication Challenges

- Confirming an expectation of low release
- Conveying meaning of “low” in comparison to “detectable” and “levels that show effects in animals”
- Demonstrating safety of material choices amid public (and regulatory) perceptions that “nano is dangerous” and “carbon nanotubes are asbestos like”
  - *Un-ringing a bell:* How can you say “this particular CNT is not asbestos-like” without saying “asbestos”?

What To Do?

- Establish a “cross-material” dialogue with regulators on safety: and ***show*** the dialogue publicly.
  - DTSC is providing a platform and an audience
- Build coherent public awareness of the generalized properties and uses that limit risk.
- Generate data to confirm low releases and environmental presence from the uses.
- Show that safe choices are made in materials, uses, and risk protections.

Repeat - Let's Not Forget

- Public posting of information – *on safety of products coming into the market now and in critical R&D pipelines*
  - Lack of response to "knowledge of presence and knowledge of safety" is not a good thing…
  - Lack of response ignores data that is responsive, and ignores an opportunity to start a positive dialogue
  - Be ready to respond to questions and press releases
- Inter-relationship of this action with other processes
  - Green Chemistry Initiative – an overarching regulatory scheme with AB 289
  - EPA Section 8e and Section 4 rulemaking ***in process***
  - REACH, Canada CEPA DCI, OECD data sets and reporting

Let's Not Forget *(cont.)*

- DTSC needs to demonstrate "success" with this DCI
  - What does that mean?
  - DTSC will submit response to UCLA for a critique
  - What happens if legislators conclude that this process was not successful?