***Toxics Use Reduction Institute Science Advisory Board Meeting Minutes***
***February 14, 2022***
***Virtual Zoom Meeting***
***2:00 PM***

***Members Present:*** Dave Williams (Chair), Robin Dodson (Vice Chair), Christy Foran, Heather Lynch, Lisa Cashins, Denise Kmetzo, Christine Rioux, Wendy Heiger-Bernays

***Members not present:*** Amy Cannon, Rich Gurney, Helen Poynton

***Program staff present:*** Liz Harriman (TURI), Heather Tenney (TURI), Hayley Hudson (TURI), Michael Ellenbecker (TURI), Tiffany Skogstrom (OTA), Caredwen Foley (OTA), Sandy Baird (MassDEP), Kari Sasportas (OTA)

***Others present:*** Carol Holahan (Foley Hoag ACC), Christina Bramante (Nano-C), Jerome Lang (Nano-C), Raza Ali (ACC), John Monica (Offit Kurman), Katherine Robertson (MCTA), Tom Lada (Nano-C), David Jones (LSI)

***Welcome & Introductions***

The chair noted that this meeting is being conducted remotely, consistent with An Act Extending Certain COVID-19 Measures Adopted during the State of Emergency. This Act includes an extension, until April 1, 2022, of the remote meeting provisions of Governor Baker's March 12, 2020, Executive Order resulting from the outbreak of the 2019 novel coronavirus, known as “COVID-19."

Board members introduced themselves, program staff were announced, and attendees were asked to put their name and affiliation in the chat.

***Approve January Meeting Minutes***

A motion was made to approve the January meeting minutes as written, and there was a second.

There is a grammatical error under pulmonary toxicity on page 2, under the first bullet there is both a period and dash. Also, on the bottom of page 2 under the last bullet there is another grammatical error, and this sentence will be reworded.

After a roll call vote the minutes were approved with these changes by the eight members present, with eight approvals.

***Carbon Nanotubes and Fibers Petition: Continued work focused on pulmonary toxicity of Multi-walled Carbon Nanotubes***

Heather gave an update of where the board is at with the nanomaterials discussion and the information that has been collected and received from board members so far.

Heather gave a summary of the information collected related to EPA’s Pre-Manufacturing Notification (PMN) data on nanomaterials. EPA requires PMN of all new materials. The hope was there would be a lot of good data there, but it turns out EPA only had about a dozen manufacturers provide data through that process and others were producing less than the required amount to be required to perform the 90-day inhalation study. Information was heavily redacted and not as useful as we first hoped when we

reached out to EPA. Overall EPA usually cites the study with the lowest no effect level around 1 mg/$m^3$. Pulmonary toxicity effects were considered as “plain old pulmonary toxicity” perhaps with more potency due to size. EPA stated that CNT are “known to be toxic at low levels”. EPA mentioned information and papers we have already looked at such as Beard, Pauluhn, as well as the 2013 NIOSH report as best pieces of information.

Hayley gave an update on the changes to the nano spreadsheet. The spreadsheet was updated with information on length, diameter, surface area, and any metal catalysts mentioned in the papers specific to pulmonary toxicity. Many of the studies had information on length and diameter, but information on other characteristics were less cited. We looked at studies that evaluated MWCNTs with diameters from 1 nanometer to 5 micrometers. The majority of the studies were in the range of 1-50 nm. In terms of length there was definitely a larger range - studies noted particle lengths anywhere from 200 nm up to 1 millimeter.

Liz summarized the 2020 CoRAP report from ECHA (Community Rolling Action Plan prioritizes substances for evaluation as a Substance of Very High Concern (SVHC)) on MWCNT, synthetic graphite tubular and tangled. Links were added to the chat. There was insufficient and inconclusive data, concluding that ECHA needed to first do a compliance check for missing information. The document does serve as a great gap analysis. Industry supplied a dossier that has detailed description of a few guideline studies and an inhalation study that showed lung effects. A harmonized classification and labelling recommendation for MWCNT of certain dimensions recommend for carcinogenic labelling (Carc 1B (inhalation)). Regarding definitions, ECHA does have a nanomaterial definition, but it is from 2011, and they have been recent criticisms that it is quite arbitrary and subject for change.

Heather summarized nanomaterial use information. OTA did a survey in 2018 and had responses from 14 facilities which use or plan to use and 5 facilities that manufacture or plan to manufacture nanomaterials. The uses that they cited were coatings, biomedical, semiconductors, higher ed research, and pharma – very varied uses.

A board member supplied a paper from NIOSH about hazard banding nanomaterials and trying to create an occupational exposure limit or band. NIOSH has been working on nano for a while and plans to go through dose response modeling to try and come up with some hazard bands. This work was helpful from a comparative standpoint and had useful tables with benchmark dose modeling. The bottom line for CNT and MWCNT was there is a lot more data for MW versus SW and MWCNT are fairly potent. All of MWCNT and SWCNT fell into the most hazardous bands. A board member noted that a nano informatics group in the EU is doing this research as well with the objective of sustainable production of engineered nanomaterials.

A board member summarized the work they did comparing the NIOSH document to Aschberger (2019). Table 5-3 in the NIOSH document was a table of physiochemical properties. Group 3 and 4 were the most hazardous but have a very limited number of studies. It was noted that surface area would be a helpful data point but is less often reported.

A board member summarized Gernand (2014) a meta-analysis and principal component analysis that used 15 rodent inhalation studies. It does look like length and diameter have impact but are not nearly as important as duration of exposure and maybe even metal impurity.

Heather shared her screen, so the decision-making document was visible and at this time the Board reviewed the criteria and discussed reporting thresholds.

- The nano petition requested they be considered Higher Hazard Substances (HHS) and lower the reporting threshold to 100 grams.

A visitor asked whether the intent of this conversation is to lump every CNT together and then regulate from there and whether all CNT are going to be treated the same or will they be considered individually?

- The conversation is around MWCNT as a potential category, but the bounds are up for discussion.

A board member asked how we define HHS and whether there are criteria to meet.

- It is a relative determination to everything else on the TURA list, and other HHS. The thresholds may also be a policy consideration, in particular in reference to the small quantities expected to be used.

There was discussion on whether or not to include a range of diameters, impurities, lengths, or surface area or if it would over complicate things by being too specific. There was further discussion surrounding a consensus statement of pulmonary toxicity and what to include.

The board agreed on a preliminary statement for pulmonary toxicity: "MWCNTs are known or reasonably anticipated to cause pulmonary inflammation and fibrosis."

At the next meeting, we will discuss other effects for MWCNT including cancer, mesothelioma, other lung effects, translocation, environmental effects, neurotoxicity, genotoxicity, and cardio inflammation, with the intent to vote on MWCNT.

***Visitor Questions/Comments***

There was an opportunity to have any visitor comments or questions at this time, and there were none.

***Next Meeting***

The chair made an announcement for a request for an agenda item for the next meeting as the chair is retiring in April and as a result, we will need a new chair and possibly vice chair.

Heather will send a When2Meet for a meeting at the end of March.

There was discussion around the remote meeting rule possibly ending in April and what steps may need to be taken, including a vote to allow remote participation.

A motion was made to adjourn, and there was a second; the vote was unanimous.

***Visitor Comments (inserted verbatim from zoom chat)***

14:04:58 From Tom L to Everyone:
Tom Lada - Nano-C, Inc.
14:05:31 From Raza Ali | ACC to Everyone:
Raza Ali, American Chemistry Council.
14:05:32 From Carol Holahan to Everyone:
Carol Holahan, Foley Hoag LLP

14:05:34 From Liz Harriman to Everyone:
Please put your name and affiliation in the chat for our meeting minutes. thank-you!
14:05:40 From iPhone to Everyone:
John Monica— Offit Kurman, PC
14:07:55 From Christina Bramante to Everyone:
Christina Bramante representing Nano-C
14:15:33 From Jerome Lang to Everyone:
Jerome Lang, Nano-C
14:21:38 From Liz Harriman to Everyone:
ECHA CORAP https://echa.europa.eu/documents/10162/801e9ee1-1347-0072-44a5-b044510e79b5
14:21:49 From Liz Harriman to Everyone:
Registration Dossier - Tangled Multi-Walled Carbon Nanotubes
https://echa.europa.eu/registration-dossier/-/registered-dossier/26129/1/1
14:22:03 From Liz Harriman to Everyone:
repeat dose subchronic inhalation study under TSCA 5e consent order:
https://echa.europa.eu/registration-dossier/-/registered-dossier/26129/7/6/3
14:22:26 From Liz Harriman to Everyone:
ECHA nanomaterial definition (from 2011)
https://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm
14:23:55 From Liz Harriman to Everyone:
A CLH proposal for rigid MWCNT with WHO fibre dimensions ( Length > 5 µm, diameter < 3 µm and aspect ratio (length/diameter) > 3) according to Carc. 1B (inhalation route) and STOT-RE 1 (lung) has been submitted to ECHA by the DE CA in 2019.
https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18195a284
14:52:00 From Christy Foran to Everyone:
Table with the example OELs from the NIOSH is Table 3-1.
14:53:31 From Liz Harriman to Everyone:
the Decision-making document Heather is showing:
https://www.turi.org/TURI_Publications/TURI_Methods_Policy_Reports/Decision_Making_under_TURA._Updated_October_2018
15:07:18 From Robin Dodson to Everyone:
Here is the TURA list of higher hazard chemicals:
https://www.turi.org/Our_Work/Policy/TURA_List/Higher_Hazard_Substances
15:53:44 From Christy Foran to Everyone:
Dave -- Thank you!!!