

U.S. Consumer Product Safety Commission

LOG OF MEETING

SUBJECT: Meeting of the ISO/TC 229 Committee (Nanotechnology)

DATE OF MEETING: May 13-22, 2020

PLACE OF MEETING: Teleconference

LOG ENTRY SOURCE: Joanna Matheson (HSTR)

COMMISSION ATTENDEES: Isaac Mireku (LS), Joanna Matheson (HSTR)

NON-COMMISSION ATTENDEES: Contact ANSI for a complete list.

SUMMARY OF MEETING:

With the cancellation of the May 2020 Washington DC face-to-face meeting, the ISO Technical Committee 229 (ISO TC/229, nanotechnologies) working groups met via teleconference the week of May 18, 2020, to discuss high priority projects and work items that are near publication. Staff participated in Working Group 3 (WG3, Health, Safety and Environmental Aspects of Nanotechnologies) and Working Group 5 (WG5, Products and Applications) meetings. The proposed fall TC 229 Plenary week, currently scheduled to be held in London in November 2020, may be virtual.

WG3 held additional meetings on May 13-14, 2020. On Wednesday, May 13, 2020, WG3 held a general meeting to review the current status of all WG3 projects, receive an update on coordination with the OECD and European Center for Standardization (CEN/TC 352 (nanotechnologies) and CEN/TC 137 (workplace exposures)), and review the WG3 Roadmap including outreach activities. The WG3 Roadmap was discussed further on Thursday, May 21, 2020. The WG experts supported adding advanced/emerging methods and materials to the WG scope; the experts noted that they are already dealing with these materials. It was suggested to consider adding relevant standards activities on the safety of nano-enabled products developed to fight the coronavirus.

For projects recently added to the WG3 work program, the intention is to hold web-based meetings within the next two months to begin development of those projects. Presentations were given on two proposed projects, *Development of an evaluation method for chronic inhalation toxicity based on the lung burden of nanomaterials*, and *Dermal toxicity assessment of textiles containing manufactured nanomaterials*. The inhalation study is based on lung burden over time, not daily aerosol concentration. This method is intended to be cheaper, smaller and easier to use. It was noted with the dermal toxicity project that relevant OECD Test Guidelines were cited and there was discussion whether these guidelines need to be adapted to be useful for nanomaterials.

In addition, it was suggested that this project could focus on the characterization and extraction of nanomaterials in textiles and noted work occurring with other ISO technical committees. Discussions on May 14, 2020, were on the preliminary work item *In vitro nanoparticle phototoxicity assay*, a project co-led by the US and Korea. The draft document was presented, methodology discussed (e.g., dispersion materials, light source, potential wavelength interference), and it was noted that the interlaboratory study is set to begin, with NIST as one of the participating laboratories.

On Monday, May 18, 2020, WG3 met to discuss technical report (TR) 22455, *In vitro 3D culture for cytotoxicity of nanoparticles*. The project leader addressed comments received from the recent ballot, including lack of discussion contrasting 2D and 3D cultures, the high concentrations used, false positives and false negatives due to optical properties of some nanomaterials, and lack of robustness of the introduction. The expectation is that this work item should be ready for publication in 2021. The 2nd WG3 session was a ballot resolution meeting on DTR 22293, *Evaluation of methods for assessing the release of nanomaterials from commercial, nanomaterial containing polymer composites*. This large international project is nearing completion, comments received from the recent ballot were addressed and clarification from co-authors is needed on a few points.

On Tuesday, May 19, 2020, WG3 met to discuss technical standard (TS) 21633, *Label-free impedance technology to assess the toxicity of nanomaterials in vitro*. Comments were addressed, further refinements made, and the standard is ready for ballot. The 2nd session focused on TS 12901-1, *Occupational risk management applied to engineered nanomaterials Part 1: Principles and approaches*. The project leader made a request to set up focus groups to address the large number of comments (e.g., update references, address fire/explosion risk, exposures from unintentional releases, use of read across/grouping) and many of the WG experts agreed to participate.

Wednesday, May 20, 2020, WG3's 1st session met to discuss the proposed TS 19337, *Characteristics of working suspensions of nano-objects for in vitro assays to evaluate inherent nano-object toxicity*. The project leader has characterized more than 50 types of nano objects. Meeting participants volunteered to help in the further development of the standard. The 2nd session discussed the recent updates to DTR 23463, *Characterization of carbon nanotube and carbon nanofiber aerosols in relation to inhalation toxicity tests*. More than 81 comments were received on the last circulated draft document, most were addressed, and WG experts will help with revising text. This standard should be ready for publication in 2021.

On Thursday, May 21, 2020, WG3 held joint sessions with WG5 to discuss preliminary work item (PWI) 23652, *Considerations for Radiolabeling Methods of Nanomaterials for Performance Evaluation*. This project was originally part of a biodistribution assay, which was divided into two parts in 2018. The project leader addressed new comments (e.g., added in sections on *in vitro* and *in vivo* stability, added relevant ISO references) and will revise the manuscript by the end of July and circulate the updated document to

the WGs. The joint session also discussed TS 23650, *Evaluation of the Antimicrobial Performance of Textiles Containing Manufactured Nanomaterials*. The project leader reviewed the recent comments (e.g., terms such as “nonwoven fabrics”, inclusion of other sources to the Annex such as the US Pharmacopeia) and responses. The WG agreed to the changes and recommended balloting resolution.

WG3 met on Friday, May 22, 2020 to discuss *Radiotelemetry-spectral-echocardiography based real-time surveillance protocol for in vivo toxicity detection and monitoring of engineered nanomaterials (ENM)*. The project leader is looking for additional experts to help in the development of the document, prior to this meeting there were only four experts (two from the US) who volunteered. This work item is one of the first projects to assess an adverse health effect endpoint.

WG5: WG5 met on Monday, May 18, 2020, to discuss comments on the PWI 23366 *Performance Evaluation of Quantification Methods of Bio-molecules using Fluorescent Nanoparticles*. Comments included questions on the definitions of aggregate, agglomerate, reference material, and quality control material. The WG discussed which definitions were appropriate for this document. WG5 experts also pointed out that the bond among quantum dot particles depends on the coating layer and may be caused by both strong (e.g. ionic bonds) and weak (e.g. van der Waals forces) interaction, a point not addressed in the document. The WG supported changing the document to a TS.

WG5 met Tuesday, May 19, 2020, to discuss NP 23367 *Performance Characteristics of Nanosensors for Biomolecule Detection*. In response to questions posed by the WG, the project leader will add text to describe analytical performance characteristics such as repeatability, stability, and signal-to-noise. WG members also indicated the need to refer to reference documents of existing ISO standards. There was a lot of interest in this project for its relevance to the use of nanosensors with the COVID-19 pandemic. The WG pointed out the applications for nanosensors should be described in more detail (e.g., food quality, environmental and safety monitoring).

On Wednesday, WG5 met to discuss PWI 4971 *Performance Evaluation of Nanosuspension Containing Clay Nanoplates for Quorum Quenching*. Quorum quenching is anti-microbial activity displayed by these nanoscale silicate platelets. The WG was concerned whether there is a correlation between the quenching ability by surfactants and the antimicrobial performance of clay nanoplates, and suggested adding some test data as an example to show the correlation. Many of the WG experts volunteered to participate in this project.

On Friday, WG5 met to discuss PWI *Nano-enabled Superhydrophobic coating: characteristics and performance assessment*. There was active discussion on the use of the term superhydrophobic, and it was suggested to consult with WG1 to work on its definition. In addition, the WG recommended to limit the scope.