

NIA 8th Annual Symposium, March 2019

Industry, Regulators and Academics working together towards sustainable and profitable nano-enabled solutions

Event reported by Claire Mays, NanoFASE, and NanoSafety Cluster Dissemination Group

Question: Where can you meet twenty NanoSafety Cluster (NSC) projects¹ and one Project Officer without going to a NanoSafety Cluster meeting?

Answer: At the Nanotechnology Industries Association (NIA) 8th Annual Symposium!

Brussels Rue Royale was the place to be on 27 March 2019 when NIA Director General **Claire Skentelbery** and Director of Regulatory Affairs **David Carlander** welcomed about 50 industry representatives, regulators, EC officials and academics to the [8th NIA Annual Symposium](#). Eleven high-level speakers took all these stakeholders on a state-of-the-art tour of issues, concerns and perspectives in nano innovation and safety. Panels, a roving microphone, and relaxed coffee/meal breaks made for real opportunities to talk, explain the Cluster project exhibits, and network. The Symposium was thus a significant Cluster dissemination event.

In the opening session, '*Nanotechnology into the future*',

- **Vera Chetty** (NIRI) started with an example of 'Nano in action'. She gave a clear exposition of the scientific challenges and engineering solutions found to inject, incorporate, or disperse nanoparticles in nonwoven textiles. Chetty's organisation advises nanoproducers envisioning novel applications, and nonwovens producers looking for breakthrough materials.
- **Carlos Eduardo Lima da Cunha** (EC) –well-known to the Cluster as Cadu—situated 'Nano in Europe' through multiple variations of a mind map with Governance at its centre. Cadu argued that nano is no longer an exotic chick, but a full-fledged advanced material (AM); scalability, marketability and Open Innovation Test Beds are appropriate concepts when moving towards a new endpoint of 'Sustainability by Design' delivering safe products to European consumers. In his view nanomaterials (NM) and AM call for a unified regulatory approach. He highlighted community-building between NSC – of which 'Europe is proud', the OECD Malta Initiative and next, the EPP Network of European Testbeds. Cadu stressed the need to bring in civil society perspectives and perceptions and address trust building, for which transparency (here, information sharing) is a key tool.
- **Hilary Sutcliffe** (SocietyInside) took up the 'Nano in Society' theme, sharing findings from TIGTech, a social research partnership sponsored by the World Economic Forum and

¹ In the 'Project Corner': caLIBRAte, CARMOF, EC4SafeNano, Gov4Nano, HISENTS, INSPIRED, INTEGRAL, M3DLoC, NanoCarb, NanoCommons, NanoFASE, NANOAGENTOOLS, NanoID, nanoInformaTIX, NanoReg2, NanoSTREEM, NECOMADA, npSCOPE, PATROLS, SmartNanoTOX.

Fraunhofer. Civil society expectations for nanosafety governance look largely sensible: no needless products – labelling for transparency – what are the personal and sustainability benefits of a nanoenabled product – what are the risks and who is looking after them? As for trust building, she quoted the pragmatic recipe of political philosopher Onora O’Neill: Be trustworthy, and show evidence of trustworthiness!

- **Gregor Schneider** (RAS AG) addressed ‘Nano in Business’, showing the interplay of science, regulatory awareness and business sense when stewarding the development of nanosilver biocides. Clients will not check hundreds of pages of safety dossiers, but need convincing assurance that the particle producer’s data and risk assessment are correct. Schneider mapped topics on which clients have concerns and distilled the messages that producers must be prepared to convey in reply (see text box). He ended

Aspects of NM production	Client’s concerns	Producer reply message
Development phase	<i>Why use NM?</i>	USP particle size, unique properties, durability
Particle release	<i>Will functionality be lost?</i>	Laundry tests, exposure scenarios
General toxicity	<i>Risk profile of the NM?</i>	Substance dossier, sensitisation assays
Marketability	<i>Active substance OK in EU for this claim?</i>	EU BPR528/2012 compliance, confirmation
Availability, constant quality	<i>Will supply falter?</i>	QMS ISO certified, Patent on production process

Adapted and generalized from Gregor Schneider (RAS AG)

with a compelling example of benefit-centred communication by Vileda about a nanosilver enabled washrag. Once rinsed the moist rags stay free of bacteria for next-day use, saving dryer energy, and reducing rewetting and prep time: significant sustainability features in an industrial environment.

In Session 2, ‘Regulation and standards priorities’,

- **Abdelqader Sumrein** (ECHA/EUON) gave a ‘Regulator’s view’ on three key, complementary policy developments. The 2011 EU recommendation for the size-based definition of ‘nanomaterial’ is under review but no core changes are foreseen, only clarifications; concepts and terms are examined in the February 2019 report by JRC-Ispra. The EC’s recently adopted revision of REACH information requirements for nanomaterials and nanoforms will come into force in 2020; focussing on Chapter R6 (Chemical Safety Analysis - QSARs and grouping) and PG (preparation of registration dossiers that cover nanoforms), ECHA will update (non-binding) guidance on the ‘best/safest way’ for companies to meet the requirements, fast-tracking work on read-across guidance to align with the new terminology of forms and sets. Finally, Sumrein spoke of the EU Observatory for Nanomaterials as a highly cost-effective tool to increase market transparency. By June it will be searchable by NM to access data on REACH registration, Cosmetic notification, and national inventories.
- **Kai Paul** (Blue Frog Scientific Ltd) gave an ‘Industry view’, showing the potential for a consistent ‘use map’ methodology to pinpoint registration liabilities/check compliance across the entire NM life cycle. Existing regulatory building blocks can be used to demonstrate how novel protocols (including Safe by Design concepts) could directly translate into regulatory language. Using tier 1 safety assessments that incorporate

worst-case conservative assumptions; Paul walked the audience through a ‘tier 1.5’ safety assessment, for which refinement of exposure based on enhanced knowledge provides a much more realistic and feasible product regulatory scenario.

- **Denis Koltsov** (BREC Solutions) reflected on ‘Nanostandards—Evolution and revolution’, highlighting the utility of standardization by displaying the international panorama of electrical outlets/plugs. He provided a snapshot of intensive consensus-based development of standards allowing producers to ‘prove that what you have is graphene and not just some two-dimensional structure’. Koltsov also mused on nano market development, providing graphs contrasting the ‘initial overestimate’ of the early 2000’s shooting vertically from 0 to 100Bn US\$, and a ‘rational enthusiasm’ 30° climb to the \$100Bn ceiling by 2035.
- **David Carlander** (NIA) reported from the ‘Global Regulatory Working Group – NIA Member priorities within regulation’. While the nano definition is under review, there will be no public consultation at this stage as it falls into the period of European Parliament elections and the installation of a new Commission next fall. As for the ‘set of similar nanoforms’ approach in Annex IV, NIA has submitted 80 comments to the first Partner Expert Group (PEG) round for which ECHA will meet in April 2019. Thirty-six substances have a ‘nanoform’ tickbox. NIA reviewed nano in the ECHA 2019-21 Community rolling action plan (CoRAP) list of substances. Carlander displayed the workplan of H2020 Gov4Nano to address the Malta Initiative for developing new OECD Test Guidelines. As for Safety Data Sheets, there are no nano-related changes in the recent Commission Regulation 2018/1881 of 3 Dec. updating REACH. During the discussion, Eva Valsami-Jones (chair of the NSC) highlighted the need to adapt regulatory language in e.g. the case of ‘solubility’, a term seen to have little meaning for nano.

The afternoon session was ‘*What goes around – Nano in waste*’:

- **Tobias Walser** (Vereala) gave an ‘Overview of nanowaste landscape for Europe’. He proposed a simple working definition of nanowaste as ‘discarded products containing NMs’ (distinguishing this from nanoemissions and from ‘microwaste’ popularly describing small plastic debris). According to context, nano in waste may be seen as a valued product to be recovered, or an impurity making recycling more difficult. A key challenge today is identifying the removal efficiency of NM by different full scale waste treatment options, with a particular focus on waste incineration plants. Walser detailed an experimental study looking at quantitative and qualitative findings like: characterization of materials moving through the incinerator; NM removal from flue gas; human exposure to NM in incineration plants; detection and quantification of nanomaterials in incineration residues. On the latter point, 80% of the experimental NM added to the waste went to the bottom ash while the rest was found in the fly ash (no NM emissions to the clean gas). Ideally, valuable metallics are subsequently extracted/recycled. However, the recovery of NM is challenging due to their dispersion in the incineration residues, their size, and typically their low quantity. Walser found that nanowaste can be safely treated in incineration plants with best available technology, but attention should be paid to the treatment of the incineration residues (NM recovery, NM emissions further down the line). He also called for tailored full-scale studies for e.g. exploring potential effects of nanowaste on biological waste treatment.
- **Ralf Kägi** (EAWAG) presented ‘Perspectives from research – The NanoFASE project’. Nanomaterials Fate and Speciation in the Environment, an NSC project coordinated by

C. Svendsen of NERC-CEH is preparing an environmental Exposure Assessment Framework and spatially/temporally detailed models whose knowledge underpinnings are accessible through a [clickable interface](#) on nanofase.eu. As part of the integrated look at how much nano is released from product value chains, and ‘where does what go?’, Kägi’s group [investigates the fate and transformation](#) of engineered NM in wastewater treatment plants (WWTP), municipal solid waste and sewage sludge incinerators and landfills. A nanosilver study in pilot-scale WWTP focussed on mass balance (95% of the Ag-nanoparticles were removed from the wastewater stream and accumulated in the sewage sludge) and resulting form (speciation, morphology and structural arrangement). Silver and also copper (incineration) studies revealed key transformation processes, such as sulfidation within the reactors. Thus, what goes into waste reactors is not what comes out. Results from pilot scale experiments also revealed a ‘unifying’ effect, meaning that although different form of metals (nanoparticulate vs. dissolved) were spiked to the waste reactors, the materials leaving the reactors were indistinguishable. EU countries differ in where they route sludge, and thus, different amounts of transformed NM will reach soil environments via agricultural sludge applications. Nevertheless, the biota in any case is exposed to transformed rather than to pristine particles. New avenues of study by NanoFASE scientists look at the impacts of transformation products on biota, and ask whether these impacts too are unified.

- ‘Perspectives from Industry’ were offered by **NIA Members** who shared their own processes and potential challenges in waste from an environmental perspective, with a precautionary attitude strongly in evidence here. In discussion, it was generally agreed that industrial processes consciously minimise wastage or loss of expensive NMs during production phases. (A regulated fee on the waste stream entering management systems could offer a further incentive to reduce such emissions.) Realistic cases treat nanowaste generated during usage phases or the fate and transformation of particles reaching waste management systems at end of life phases. (For usage, look at e.g. weathered fragments of nano-enabled paint rather than at a worst-case scenario of all pristine input NM released in one go). NM in stable dispersions at production stage are later subject to the efficient process of heteroaggregation; in waste reactors particles disappear/reform/reappear, often as sulfides, as described in the session’s science presentations. The empirical work is necessary to demonstrate these processes because e.g. it is impossible to identify today’s production mass of Ag against the environmental background of silver deposited by legacy photographic uses. Incineration products are not nano-specific, and conventional extraction procedures and recommendations on incineration temperatures apply.
- **David Carlander** (NIA) shared ‘Regulatory frameworks around waste – the great equaliser’ and highlighted several reports from the EC, UNEP, OECD (including comments from the Business stakeholders committee BIAC), etc. Today there is no formal definition of ‘nanowaste’ nor universally accepted regulation. The Waste Framework Directive 2008/98/EC says waste is any substance the holder discards, intends or is required to discard. Waste containing NM may emerge from manufacturing, transformation, use, and end of life phases. NMs have no specific toxicological effects. They do not represent a new type of waste category and current waste management practices are applicable. REACH dossiers must include information on substance disposal. Reduce-reuse-recycle remain the catchwords.

Finally the session presenters assembled as a panel to interact with the audience. Discussion reaffirmed that there is no clear need to focus specifically on engineered NM amongst the broad range of (natural and incidental) nanomaterials present in waste treatment. Presenters agreed however that ‘we don’t have all the answers’, and confirm the value of ongoing research on sustainable waste treatment options for complex products and advanced materials. Hypotheses are generated and tested: e.g., do NM with different product functionalities have different behaviour or outcomes in waste treatment? Today studies say no: NM do not resist physics, and ‘do what they have to do’. Differences in environmental fate are seen according to country practices (recycling points, or application of sludge to agricultural land, etc.). In industry, waste reduction is well managed, and refinements in countries with advanced waste management systems take place now at the reuse-and-recycle tip of the pyramid, showing the effectiveness of policies implemented over the last decades.

The strong presence of Cluster projects interacting with industry and regulatory representatives at the NIA 8th Annual Symposium reflected the outreach beliefs of our Dissemination Group Chair Claire Skentelbery. NSC projects’ next chance to meet multiple stakeholders face-to-face will be at **EuroNanoForum (Bucharest, 12-14 June)**, where Claire is leading the charge for a Cluster Pavilion. Upcoming in **Copenhagen, 7-10 October** will be [‘NanoSafety Cluster Week: Building Confidence in Risk Assessment and Governance of Nanomaterial Innovation’](#) (in liaison with caLIBRAte’s closing conference). (Similarly, Frank von Kammer will combine [NanoFASE’s concluding conference with ICEENN 2019 in Vienna, 1-6 September](#)).

And for those who want to stay at home while still benefitting from multi-stakeholder interactions, the Cluster will soon offer project outcomes-oriented **webinars** (hosted on our [YouTube channel](#)). Visit the NanoSafety Cluster [news/events](#) page website in April for registration information for all these initiatives.