

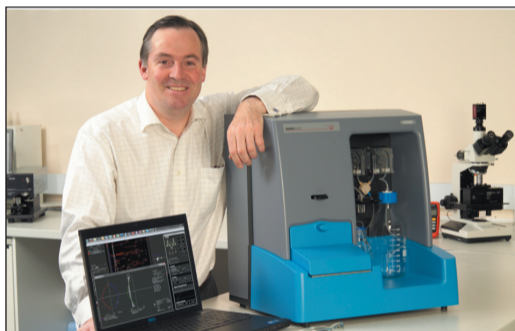
# focus on Microtechniques & Microscopy

NanoSight, a leading manufacturer of nanoparticle characterisation technology, offers the latest news and views on the EU definition on nanomaterials. CEO, Jeremy Warren writes:

## The EU Definition of Nanomaterials – An American Perspective

Jeremy Warren, CEO, NanoSight Ltd, Salisbury

Since first citations of the term 'Nanotechnology', scientific, industrial, public and political stakeholders have called for a robust regulatory framework to address the concerns surrounding these exciting new materials. It is the promise of novel and useful properties from nano sizes of familiar materials that prompts a reappraisal of our knowledge of their potential toxicological and environmental impact. The argument goes that, without public and political confidence, this new science risks fear and distrust, rather than being embraced as providing a multitude of solutions to challenges in the fields of green energy, world food production or pharmaceutical advancement, to name but a few. While Europe is already on the move on this subject, the Americas are just starting to react. We asked Professor Andrew Maynard, University of Michigan, himself a well-known and out-spoken advocate of 'sensible' nanotechnology, for his comments.



Jeremy Warren

First, some background: In October 2011 the EU Commission published a recommended definition of Nanomaterials [1]. This definition is not the complete framework, but it is a significant step towards it.

Observers of embryonic nanotechnology regulation recognised this definition as the missing jigsaw piece in planned legislation; witness the French government largely adopting the definition's wording and getting draft legislation on

compulsory labelling of Nanomaterials out for consultation in under three months. Meanwhile stakeholders in other fields, including nanomaterial manufacture and workplace exposure, handling, labelling, transportation and environmental fate, now find they have an authoritative definition to slot into nascent regulation.

### The key points of the definition are these:

- 1) It is a Nanomaterial if any of these three criteria are met:
  - a) At least 50% of the particles by count have one external dimension between 1 and 100nm.
  - b) The material has a surface area greater than  $60\text{m}^2/\text{cm}^3$ .
  - c) The substance appears on an 'include' list that captures materials such as graphene, which would otherwise fall outside the definition.
- 2) The definition includes naturally-occurring as well as manufactured and incidentally manufactured particles.
- 3) There are no specific recommendations on characterisation methods to meet these specifications.
- 4) The definition is a recommendation, not a regulation; however its provenance bestows authority.

Despite protracted and energetic attempts by SCENIHR (the Scientific Committee on Emerging and Newly Identified Health Risks, part of the Directorate General for Health and Consumers) to draw stakeholders into consultation, much of industry and the scientific community appear taken by surprise here. One can sympathise with the compliance officers in, for example, tyre manufacturers or cement producers who suddenly find themselves within the nanotechnology industry.

### Jeremy Warren, NanoSight CEO, comments:

"Sympathise one might, but reading back through SCENIHR's publication, 'Scientific Basis for the Definition of the Term 'Nanomaterial'', they describe in depth the reasoning behind the definition. SCENIHR exhaustively discuss the possible measures and their benefits, and make clear the large areas of ambiguity and difficulty in these judgments. Then, with some moral courage, they draft this definition, and in doing so take a step forward in supplying the urgent need for regulation.

"The 100nm upper limit is essentially historic, coming from original definitions in nanotechnology. It was arbitrary then, and is so now, but it is a starting point. Given this definition is specific to regulation, these numbers have to be precise to be enforceable. Specifying count rather than weight per cent recognises that chemical reactivity increases per mass dose for smaller particles. Parameters more closely relating to potential toxicity are missing – these are likely to follow on from this initial size-based definition. Regarding the lack of recommended characterisation methodologies, one need look no further than diesel combustion emissions or the water industry for precedents, where regulatory need sets scientists a measurement challenge – and maybe that is the right way to drive development of practical measurement methodologies?"

"Let me clearly state my interest here – NanoSight's NTA (Nanoparticle Tracking Analysis) is at least a partial solution to the nanoparticle counting requirement, and in combination with occasional electron microscopy to inform the bottom end of the 1 – 100nm range, we have a unique and practical, readily-implementable solution.

"As the dust settles following the initial publication, reflect on the significant positive drivers from industry in support of legislation; big business surely seeks to see nanotechnology de-risked? Potential adverse public reaction hangs over nanotechnology, limiting investment and curbing strategic intent. More cynically perhaps, big business deals better with regulation than SMEs; here is a barrier to entry that will ultimately lead to profitability in this sector."

### Views from across the Atlantic

With North America clearly embracing nanotechnology through a decade of investment initiatives, we wanted to learn how this EU definition will be viewed by US industry and science. We spoke with Professor Andrew Maynard.

Andrew Maynard is the Charles and Rita Gelman Risk Science Professor at the University of Michigan School of Public Health and is Director of the University of Michigan Risk Science Center. His work focuses on the responsible development and use of emerging technologies, and on innovative approaches to addressing emergent risks. He has testified on a number of occasions before congressional committees on nanotechnology, served on National Academy panels and other advisory boards, and is a member of the World Economic Forum Global Agenda Council on Emerging Technologies.

"I have been a rather outspoken opponent of the EU definition since its release – worrying that it is informed less by science and more by a political desire to codify assumed changes in material behaviour below 100nm. Despite SCENIHR trying extremely hard, they struggled to justify a definition of engineered nano material on the basis of evidence alone. The committee's report left the impression that they established



Professor Andrew Maynard

a basis for a definition because this is what they were told to do, not because they believed this is what the science dictated. And while it is often assumed that black and white definitions are needed for regulatory purposes, this is not always the case – for example the US Food and Drug Administration has so far resisted the temptation to compromise its effectiveness through adoption of a definition of convenience rather than science. Even if definite numbers were applicable here, I am far from convinced that the numbers in the EU definition help anyone - especially when applied to any source of nano material. Is nanoscale sea spray to be regulated for instance?

Nevertheless, let's look at this from a slightly different angle. Let's say the writing is on the wall for the need to measure particle number at small sizes, and as the demand grows, so the need for viable techniques will grow. Irrespective of whether you buy into the EU definition or even agree with the science underpinning it, it is being adopted and is likely to be applied increasingly within Europe. And this will have knock-on effects for companies trading in Europe, as well as products marketed in the US. How long will it be before US and Canadian regulators follow suit out of expedience if nothing else - maybe not along the precise lines of the EU definition, but nevertheless one that demands that manufacturers measure and report on the number of particles below a certain size in their products? And as they do, how will manufacturers measure nanosized particles in products to the required

levels of accuracy and precision? As Jeremy and his colleagues have said, this story is going to run and run."

### Where next?

Warren concluded: "I welcome this definition as a starting point to deliver regulation on potential toxicity. There is much research work to be done, and having this definition, this building block in place, will surely enable government investment in research to go the next step, from simple physical parameters to the far more complex challenges of bioavailability and bio interaction at the heart of toxicology. If industry and regulators can get this right, then far from labelling 'contains nanomaterial' being in the smallest permissible font, we might see 'Contains Nano' in a bright splash of colour, implying progressiveness, advanced and useful technology, and above all, trustworthiness."

### Reference:

1. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF>

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