# ANSI-NANOTECHNOLOGY STANDARDS PANEL (ANSI-NSP)

# REPORT FROM ADVANCED MATERIALS WORKSHOP

AUGUST 19-20, 2020

# Contents

# I. Introduction

ANSI's Nanotechnology Standards Panel (ANSI-NSP) was established in 2004 at the request of Dr. John Marburger, then Director of the Office and Science and Technology Policy (OSTP) to coordinate the development of standards, including nomenclature, in the area of nanotechnology. The ANSI-NSP itself does not develop standards, but works to facilitate communications between Standards Development Organizations (SDOs) engaged in the development of nanotechnology standardization. The ANSI-NSP also identifies priority areas of nanotechnology standardization and potential organizations to assist in the development of relevant standards.

In August 2020, the ANSI-NSP convened a Workshop focused on "Advanced Materials", a term that has not yet been defined formally. This Workshop was organized with the hypothesis that standards development organizations (SDOs) involved in nanotechnology standardization should consider expanding their efforts beyond nanotechnology to include substances described as Advanced Materials. The ANSI-NSP offered this hypothesis to encourage participants to consider it and formulate a response. The ANSI-NSP also recognized that many of the standards and related practices developed for nanomaterials can be applied to many substances referred to as Advanced Materials.

The ANSI-NSP invited a number of technical and policy experts to consider the issue of Advanced Materials and how relevant organizations could or should play a role in the development of standards needed within the community. The ANSI-NSP leadership did not expect to resolve all of the issues raised by the end of the Workshop, but instead hoped to identify a direction for potential next steps. This Workshop summary includes the materials presented during this meeting, answers questions posed during the discussions and identifies suggestions brought to the table by participants.

# II. Symbols and abbreviated terms utilized in this Report

| | |
|---|---|
| EHS | environmental, health and safety |
| EU | European Union |
| ANSI-NSP | ANSI Nanotechnology Standards Panel |
| OECD | Organization for Economic Co-Operation and Development |
| SDO | Standards Development Organization |

# III. U.S. Perspectives Relative to Advanced and Emerging Materials

The three panels on Day One consisted of United States representatives from four stakeholder sectors: Government, Industry, Academia, and Non-Governmental Organizations. While panelists were asked to provide their perspectives on Advanced Materials, they were not instructed to either support or oppose the position put forward by the ANSI-NSP leadership. The only request made to panelists was to connect their comments to the importance and necessity of standards. Many panelists did express support for the position that SDOs engaged in the development of nanotechnology standards should also be engaged in the development of standards for Advanced Materials, and identified potential standards needed, but they acknowledged that greater engagement from the standards community was needed for Advanced Materials, including from industry-specific committees.

## Panel 1: U.S. Government Agencies

The following Panelists presented U.S. government perspectives on the issue of Advanced Materials and potential standards requirements:

- Dr. Treye Thomas, Consumer Product Safety Commission
- Dr. Charles Geraci and Dr. Gary Roth, National Institute for Occupational Safety and Health
- Dr. Albert Davydov, National Institute of Standards and Technology
- Dr. Alexandria Stanton, U.S. Environmental Protection Agency
- Dr. Anil Patri, U.S. Food and Drug Administration

The Consumer Product Safety Commission (CPSC) was concerned about the current and future use of emerging and enhanced materials in consumer products and the potential new hazards and risks associated with such materials. Standards in these areas could help identify and address such risks. Dr. Thomas suggested that it would be beneficial to determine how other organizations and groups were defining such materials.

NIOSH considered Advanced Materials to be those materials designed with specific functionality in mind. "Old" materials and processes could become "new" or "advanced" as they were improved. However, there was the concern that more "active" materials correlated to more hazard; and, if so, additional handling procedures would be required to protect workers.

Dr. Davydov commented that for him, Advanced Materials exhibited novel or enhanced properties, which improved performance over conventional products or processes. These materials were not necessarily new, but were utilized in a different way. Standardization for Advanced Materials was needed, including to establish the relationships between "structure, property and performance;" to standardize emerging technological processes, and to consider environmental health and safety issues surrounding Advanced Materials that could be different from nano- or micron-scale materials.

The U.S. EPA was focused on industrial chemicals and the Toxic Substances Control Act (TSCA). Dr. Stanton noted that while the EPA was currently not seeing many materials that could be categorized as "Advanced Materials," many existing nanomaterials might be considered to be "advanced". Dr. Stanton suggested that while a definition for Advanced Materials would be helpful to make the distinction between nanomaterials and Advanced Materials, it would also be useful to understand what materials the rest of the world considered to be "Advanced materials."

Dr. Patri commented that the discussions from this meeting were similar to those in the inaugural meeting of ANSI's Nanotechnology Standards Panel in 2004. Dr. Patri noted that the FDA was seeing more drug applications where the developing drugs were more complex; such applications could be based on Advanced Materials. One such example is liposomes, which many individuals/groups considered to be an advanced material. He suggested that standards would not only be needed for Advanced Materials and processes but also for reference materials to be developed relative to specific Advanced Materials.

**Participant Discussion**

Meeting participant Mr. Terrance Barkan of the Graphene Council noted that a challenge with Advanced Materials is that the category is a moving target. These were novel materials that were constantly being changed, modified, perfected and had not yet found their long-term commercial applications…therefore, it was uncertain which (materials) could be scaled or become commercially viable. He further added that standards development was a milestone on a material maturity curve and therefore organizations run the risk of trying to set standards prematurely… it would be an ongoing challenge to set standards for a class of materials that was still quite young and not established.

Dr. Bill Bihlman (Aerolytics, LLC) supported Mr. Barkan's comments, adding that the objective of standards is to help commercialize materials/processes, leading in the direction of a commodity. Drawing the line of when that should happen is difficult, noting similar challenges with additive manufacturing in the area of aerospace.

## Panel 2: U.S.-based Industry experts

The following Panelists presented industrial perspectives on the issues surrounding Advanced Materials and potential standards requirements:

- Dr. Bill Bihlman, Aerolytics LLC
- Dr. Scott Brown, Chemours
- Dr. Max Montano, Intel Corporation
- Dr. Mark Banash, Neotericon

Dr. Bihlman noted that the aerospace industry was interested in Advanced Materials and Advanced Manufacturing for utilization in aerostructures and aeroengines. Materials were evaluated for their performance characteristics. Aerospace design considerations include: cost effectiveness, strength and stiffness of the material versus weight and manufacturability. Dr. Bihlman suggested that Advanced Materials were not only new or improved materials. They could also be better grades of existing materials (e.g. of higher purity).

Dr. Brown observed that the term Advanced Materials is a general descriptor for materials with improved properties. They are defined by performance and not by size, as was the case with nanomaterials. Advanced Materials could also change over time, and evolve from being considered an advanced material to being classified as a more "conventional" material.

Standards in this area could help to provide clarity to these considerations; particularly standards in the areas of terminology. The term "Advanced Materials" is a moving target, similar to the term "nanotechnology" (i.e. "unique and novel"), which was one of the major catalysts for establishing the ANSI-NSP. Dr. Brown noted that SDOs involved in nanotechnology could help initiate work in this area but broader participation would be needed from industry-specific SDOs.

Dr. Montano commented that Advanced Materials were often included in procurement considerations. For those purposes, such materials were developed based on performance and how they were defined. As an example, ultra-pure materials, such as sulfuric acid, is considered Advanced.

In terms of standards, Dr. Montano suggested that standards could help in procurement to enable suppliers to better understand customer needs. While there were already standards available for auditing material suppliers that may be providing Advanced Materials, voluntary consensus standards could be helpful to reduce audit costs. It would also be helpful to develop purity standards for limit of detection.

Dr. Banash noted that standards are needed for Advanced Materials in the areas of taxonomy, processes, design, metrology and material specifications. He added that the lack of such standards has resulted in the "Wild, Wild West" in terms of characterization and measurement. Standards could help in developing functionalization and determining performance of such materials.

## Panel 3: Academic and Non-Governmental Organizations

The following Panelists presented both academic and NGO perspectives on the issues surrounding Advanced Materials and potential standards requirements:

- Dr. Mark Wiesner, Duke University
- Dr. Monita Sharma, People for the Ethical Treatment of Animals
- Dr. Jenny Roberts, Society of Toxicology, Nanoscience and Advanced Materials
- Dr. Bob Hamers, University of Wisconsin-Madison

In terms of how nanotechnology standards could serve as "lessons learned" for Advanced Materials, Dr. Wiesner noted that standards contribute to improving information and reducing uncertainty. Standards that could be needed relative to Advanced Materials include characterization, functionalization, ontologies and EHS requirements, which would all collectively help reduce uncertainty in this space.

Dr. Sharma noted that that this topic is not necessarily new. She noted a definition from Kennedy, et al – 2019, that Advanced Materials were materials with novel, unique properties relative to conventional materials.

She agreed with the ANSI-NSP hypothesis that SDOs developing nanotechnology standards should be involved in the development of Advanced Materials, as there are many potential synergies between the two technologies. She further suggested that additional work is needed to identify gaps and that new-approaches are needed to evaluate Advanced Materials without using animals.

Understanding the relationship of material properties and toxicity is a critical goal. In recognition of the importance of Advanced Materials and the synergies between such materials and nanomaterials, Dr. Roberts noted that the Society of Toxicology (SOT) had changed the name of the Nanotoxicology Specialty Section to the Nanoscience and Advanced Materials Section.

In terms of standardization needs, Dr. Roberts commented that a clear definition of what constituted an "Advanced Material" was needed, along with relevant metrology standards. It was also necessary to focus on what the materials are, the potential exposure of such materials and the impact of those exposures.

Some discussion was had about what makes a material "advanced": time? resulting properties? chemical and physical microstructure? Unlike with "nano" materials, which are defined predominantly by size, Dr. Hamers noted that Advanced Materials are more complex. There is also a gap in understanding materials in which the chemical and physical structures together lead to emergent new properties.

**General Discussion**

Dr. Jo Anne Shatkin (Vireo Advisors) commented that "shifting focus from "nano" to "Advanced Materials" seems to move down the value chain from the ingredients or raw materials to how they are processed and used. This is important because it represents what will enter the economy, but also has implications for how governmental agencies, industry, SDOs and others might address issues of characterization and safety. It brings a more realistic focus, but adds complexity. Technologies rather than materials would require terminology, assessment and characterization. It begs the question of: 1) what additional expertise may be needed for methods development, safety evaluation. For example synthetic biology expertise. 2) Could efforts be joint with other committees?"

Dr. Thomas observed noted that organizations had been able to come up with in vitro, analytical exposure methods to be used for a range of materials, and there were applicable tools and approaches to address them.

Dr. David Ensor (IEST) commented that "one concept emerging from the day's discussion was that the traditional concepts of nanotechnology focused on the feature size of about 1 to 100 nanometers, the structure of the material was not considered. Many Advanced Materials appear to incorporate structure to improve performance."

Dr. Hamers responded that "a key challenge here was that as the degree of chemical complexity increases, the feasibility of testing individual materials rapidly becomes intractable. One needed to move beyond testing of specific materials to a paradigm based on mechanistic understanding of the biological responses and looking for how these responses are similar/different for broader classes of materials. So that means the molecular biology community needed to be involved."

Dr. Bihlman suggested that "Pivoting from science (physics/chemistry/biology) to engineering, one framework to help define 'advanced' is NASA's TRL (technology readiness level). This maps commercialization of technology, in general. This metric spans from 1 to 9, where 1 to 3 is considered burgeoning, and perhaps in our case, 'advanced.'"

Dr. Vladimir Murashov, Chair of the ANSI-Accredited U.S. TAG to ISO/TC 229 noted that some of the structural complexity in ISO/TC 229 was addressed through a term "engineered nanomaterials"

Dr. Hamers added that there is "a need for standardization of materials in the energy storage arena. Materials like the "NMC" compositions $LiNiMnCoO_2$ undergo proprietary processing and coatings that are used in their internal manufacturing but are not generally available. This complicates any assessment of EHS properties and also slows down other forms of development in the small-business/start-up sector. I'm the co-founder of a small battery company and we have great difficulty getting non-proprietary "standard" materials with known, reproducible composition."

Sanghamitra Majumdar provided a comment that "Most of the time "nanomaterials" is referred to as a whole, and that has created a very negative stigma the community; common people do realize that nanotechnology is groundbreaking and making strides in different industries, but it has also created unnecessary stigma when the products mention "Nano". This also has discouraged industries to specify (nanomaterials) in the constituents, especially in food, agriculture and consumer products. And thus we don't get to realize what is actually being added to products. Is it a good idea to include "communication" to the broader community and also clarify each Advanced Materials on its own as we develop standards and not as a general class."

## IV. International Perspectives on Advanced Materials

While Day 1 focused predominantly on U.S.-based expert positions relative to Advanced Materials, Day 2 began with a consideration of the International Perspectives on such materials and work already underway within the European Union and various regulatory agencies.

- Ms. Mar Gonzalez, Organization for Economic Cooperation and Development (OECD)
- Dr. Kirsten Rasmussen, European Commission, Joint Research Center
- Dr. Doris Voelker, German Environment Agency (UBA)
- Dr. Lisa Friedersdorf, National Nanotechnology Coordination Office

Dr. Gonzalez informed participants that the OECD Chemicals Program recently included Advanced Materials in its Scope of Work. The Working Party on Manufactured Nanomaterials (WPMN), part of the OECD Chemicals Program, was considering if it should take on Advanced Materials under its purview. Ms. Gonzalez commented that the commonly accepted range of 1 to 100 nanometers for nanomaterials was not binding on the OECD and it already considered other materials. Therefore, Advanced Materials were on OECD's radar.

The term "Advanced Materials" is popular in the literature despite not having a broadly accepted definition. The OECD itself currently does not have a definition for Advanced Materials. As an organization, they wanted to have a good understanding of what is going on globally before taking any actions. This included understanding what is different between Advanced Materials and conventional materials. They were also considering if existing tools could be applied to Advanced Materials.

Dr. Rasmussen reminded experts present of the 2019 EU policy called the "Green Deal", which indicated that innovations were desirable but they must be safe and sustainable/circular. There is also an EU chemicals strategy for sustainability. The safety information needed for Advanced Materials is similar as for other materials.

EU legislation was supported by available tools but such tools are not always relevant for mixtures, mixtures where there were synergistic/antagonistic issues (need new tools & new standards), and dynamic mixtures. Advanced Materials are more complicated to define.

Dr. Voelker provided background relative to UBA's concerns about environmental risk generally and their previous involvement with nanomaterials. This concern now included Advanced Materials; however, they currently do not have a common understanding of what materials were to be considered "Advanced"; as such materials went beyond what was referred to as first generation nanomaterials.

Relative to Advanced Materials, UBA is considering if the current EHS tools are sufficient, in addition to any regulatory challenges these materials pose and if their safe use was assured. She noted that UBA was holding a series of workshops, with two completed, focused on this issue. Key observations at this time included that for Advanced Materials: experience with nanomaterials was beneficial but broader expertise was needed, including their impact on the circular economy. In addition, defining Advanced Materials narrowly would not be helpful. It would be preferable to set limits and take advantage of clustering.

Dr. Friedersdorf commented that Journals focused on advanced materials had been in circulation for years; this was not a new area. She added that while it made sense for US organizations and other bodies to expand their nanomaterial work to include Advanced Materials, in her opinion that did not mean the standards community was ready to create standards for these new materials. This was not an opposition to the standards work, but rather a perspective on whether the market was ready for standards. As an example, the lack of an established and acknowledged definition for "Advanced Materials" is an issue. That being said, she acknowledged that the work being done in the various SDOs, and frameworks developed in nanomaterials standards could be informative.

# V. Review of Thought Starter on Advanced and Emerging Materials

***See ANSI-NSP thought starter contained in Annex B***

# VI. Standards Development Organizations: Opportunities and Challenges Relative to Standards for Advanced and Emerging Materials

- Dr. Debra Kaiser, Chair of ASTM E56 Nanotechnology, National Institute of Standards and Technology (NIST)
- Dr. Vladimir Murashov, Chair of the ANSI-Accredited U.S. TAG to ISO/TC 229 Nanotechnologies, National Institute for Occupational Safety and Health (NIOSH)

Much of ASTM E56's work relied on interlaboratory testing to develop and standardize their methods.

While the ASTM E56 leadership had considered the ANSI-NSP position that SDOs working in nanotechnology standards should expand their work to cover Advanced Materials, they concluded that for E56 this was not a good idea. This position was taken due to the fact that many ASTM E56 standards were not extendable to include Advanced Materials because they are either material-specific, size-limited, or sample-specific. In addition, ASTM E56, like many SDOs, has a shortage of volunteers so adding more work could stretch the present volunteers too far.

As Advanced Materials could be based on nanomaterials, Dr. Murashov agreed with the ANSI-NSP thought that it would be appropriate to include standards for Advanced Materials in existing bodies already considering nanomaterials (e.g. those materials where size >100 nm). A number of the Working Groups within ISO/TC 229 *Nanotechnologies* were already considering Advanced Materials within their work programme and while Advanced Materials is already implicitly included in the scope of the TC, specifically stating the inclusion of Advanced Materials could increase enthusiasm and bring in additional expert volunteers.

Dr. Murashov suggested that the horizontal structure of TC 229 would also help address cross-cutting issues that come up with respect to commercialization.

**General Discussion**

Dr. Shatkin commented that Dr. Murashov presented a compelling value proposition, that there could be a shift from the focus on size, which has not turned out to be a very useful categorization. A focus on advanced materials standards would shift focus to the properties that challenge traditional chemicals paradigms for characterization and safety/regulatory evaluation.

In response to a comment from Dr. Patri requesting clarification on a statement relative to ISO/TC 229's consideration of Advanced Materials, Dr. Murashov noted that Advanced Materials were considered a product of nanotechnologies according to the TC 229 scope. In his opinion, nanomaterials were in general a subset of advanced materials.

Dr. Davydov suggested that as Advanced Materials could be defined as materials with novel or enhanced properties that were not size-dependent (for example quantum materials such as bulk topological insulators), then nanomaterials would overlap with Advanced Materials on a Venn diagram rather than being a subset of Advanced Materials.

Dr. Kaiser noted that there were existing committees that were using active advanced materials and industrial biotechnology and biomaterials. Dr. Clancy added that it would be useful to learn more about those committees' existing efforts.

Dr. Brown commented that there could be friction in developing a definition for Advanced Material. It would be appropriate to explain how standards could apply in each individual situation, across disciplines, industries and use cases. Dr. Patri added that there had to be a reason for standards, such as regulatory or industry needs. It would be necessary to consider such use cases and materials when developing such documents.

Dr. James Ede (Vireo Advisors) highlighted "the work of the Advanced Materials and Technologies Specialty Group (AMTSG) at the Society for Risk Analysis (SRA), which is aiming to advance the risk analysis of Advanced Materials. This group recently decided to expand its scope from Nanomaterials to include Advanced Materials and Technologies with the hope of applying some of the 'lessons learned' from Nanomaterials to Advanced Materials more generally."

Dr. Geraci noted that Advanced Materials had been evolving for decades and it was necessary to identify and classify such materials so that we can create measurements and health/safety risks to humans or the environment. Characterization methods and standards are needed to control such materials.

Some general discussion ensued, including of the following points: How to address Advanced Materials is in the startup phase in the EU. A lot is known about nanomaterials, but what can be done to ensure that the methodologies already established were addressing Advanced Materials or could be extended to address these materials? Advanced Materials cover a lot of possibilities, and could be too broad for standardization. It might be necessary to narrow down a definition for standardization and policy support with the goal of safe and sustainable materials.

Dr. Clancy noted that for standards to be of value, they had to be used. Who would be the audience for standards in Advanced Materials and how would such standards be utilized? The relevant audience may not even know how they could use these standards or if they need them yet.

It might be better identify/define emergent properties rather than Advanced Materials. The issue of marketing and perception is a bit more entrenched in 'Advanced Materials' versus a material or nanomaterial with emergent properties. This may fit in the functional property paradigm and allow bridging back to "Advanced Materials." In other words, focus on what Advanced Materials do versus what they are – properties vs substance.

## VII. Workshop Conclusions

Based on the comments from the both the panelists and workshop participants, there was general though cautious support for the suggestion that SDOs working in nanotechnology standardization could expand their work to include Advanced Materials. Some high-level reasons to support the hypothesis included:

- the observed synergies between the work done so far on nanomaterials and the future needs of advanced materials;
- the synergies in the expertise between those who are currently working on Advanced Materials and those who have worked on nanomaterials;
- the cross-functional approach taken by SDOs and their members on both nanotechnology and advanced materials; and
- most participants agreed that it is necessary to establish a definition for Advanced Materials, and potentially categorize such materials based on properties, relevant measurement methods, and potential EHS impacts.

While some support was voiced for SDOs to consider expanding their efforts beyond nanotechnology to include substances described as Advanced Materials, there were cautionary observations that should not be overlooked, such as being aware that the amount of work resulting from such an expansion of the scope of an SDO's activity could be overwhelming unless limits were agreed to. Creating a structure around a definition, creating classes of Advanced Materials, focusing on certain types of uses, etc., would help mitigate this resource concern to a degree. In addition, being aware of the importance of discipline in the use of terms, like Advanced Materials, and communication about the topic and related issues generally would be essential to making steady progress in standardization.

## Annex A: Final Workshop Agenda

ANSI-NSP
ANSI Nanotechnology Standards Panel
American National Standards Institute

**ANSI-NSP 116r3-2020**

**Date Revised**: August 18, 2020

**ANSI Nanotechnology Standards Panel (ANSI-NSP)**
**www.ansi.org/nsp**
**Advanced Materials**

**August 19, 2020**
**10.00 a.m. – 1.00 p.m. EDT**
**August 20, 2020**
**10.00 a.m. – 1.00 p.m. EDT**

Goals of the Workshop

- Identify relationship and synergies between nanotechnologies standards activities and needs relative to advanced materials?
- How can we do better at identifying the gaps and the needs relative to Advanced Materials Standards, and how do we prioritize topic areas?

***This is a draft agenda and will be adjusted as necessary until the NSP meeting***

**Day 1: August 19, 2020, 10:00 a.m. – 1:00 p.m.**

**1.0 Welcome and Discussion of Goals for this Workshop**
10.00 a.m. – 10.15 a.m.

ANSI-NSP Co-Chair Dr. Shaun Clancy will review the goals of this workshop

**2.0 U.S. Perspectives Relative to Advanced and Emerging Materials**
10:15 a.m. – 12:30 p.m.

*There will be a fifteen minute break taken at 11:30 a.m. – 11:45 a.m.*

**2.1 Inputs from U.S. Government Agencies**

i. Dr. Treye Thomas, Consumer Product Safety Commission
ii. Dr. Charles Geraci and Dr. Gary Roth, National Institute of Occupational Safety and Health
iii. Dr. Albert Davydov, National Institute of Standards and Technology
iv. Dr. Alexandria Stanton, U.S. Environmental Protection Agency
v. Dr. Anil Patri, U.S. Food and Drug Administration

**2.2 Inputs from Industry**

vi. Dr. Bill Bihlman, Aerolytics LLC
vii. Dr. Scott Brown, Chemours
viii. Dr. Max Montano, Intel Corporation
ix. Dr. Mark Banash, Neotericon

**2.3 Inputs from Academic Institutions and Non-Government Organizations**

x. Dr. Mark Wiesner, Duke University
xi. Dr. Monita Sharma, People for the Ethical Treatment of Animals
xii. Dr. Jenny Roberts, Society of Toxicology, Nanoscience and Advanced Materials
xiii. Dr. Bob Hamers, University of Wisconsin-Madison

**2.4 Q & A with Meeting Participants**

**3.0 Call to Action: Consideration of Feedback Request During Day 2 Discussion**

12:30 p.m. – 12:45 p.m.

**4.0 Day 1 Adjournment**

12:45 p.m.

**Day 2: August 20, 2020, 10:00 a.m. – 1:00 p.m.**

**Opening Speaker: Dr. Andrew Maynard, Arizona State University**

**5.0 International Perspectives on Advanced Materials**

10:15 a.m. – 11:00 a.m.

- Ms. Mar Gonzalez, Organization for Economic Cooperation and Development
- Dr. Kirsten Rasmussen, European Commission, Joint Research Center
- Dr. Doris Volker, German Environment Agency (UBA)
- Dr. Lisa Friedersdorf, National Nanotechnology Coordination Office

**6.0 Review of Thought Starter on Advanced and Emerging Materials**

11:00 a.m. – 11:05 a.m.

Dr. Clancy will provide a brief review of the Thought Starter that was distributed in advance of the Workshop.

**7.0 Standards Development Organizations: Opportunities and Challenges Relative to Standards for Advanced and Emerging Materials**

11:05 a.m. – 11:30 a.m.

- Dr. Debra Kaiser, Chair of ASTM E56 Nanotechnology
- Dr. Vladimir Murashov, Chair, U.S. Technical Advisory Group to ISO/TC 229 Nanotechnologies, Convenor of ISO/TC 229 Working Group 3 – Health, safety and environment

***10 Minute Break***

11:30 a.m. – 11:40 a.m.

**8.0 OPEN DISCUSSION: How can the lessons learned and multi-disciplinary nanotechnology standards activities be utilized for advanced materials**

11:40 a.m. – 12:40 p.m.

Questions to be considered during the open discussion include:

- Are we on the right path by using those standards organizations involved in nanotechnology?
- How do we identify standards needs relative to Advanced Materials Standards?
- How do we coordinate this work effectively amongst the groups with relevant expertise?

**9.0 Wrap-up and Next Steps**

12:40 p.m. – 12:55 p.m.

**10.0 Adjournment**

1:00 p.m.

# Annex B: ANSI-NSP thought-starter

**SDO's should expand their scope beyond Nanotechnologies to include Advanced Materials**

**The Changing Landscape:**

In the early part of the 21st century, nanomaterials were the highlighted 'advanced material' class thought to potentially revolutionize society, providing new opportunities and posing new risks. Numerous standards activities (including ISO/TC 229, ASTM E56, IEC/TC 113, IEEE, IEST and others) were initiated followed by other standards development organizations (SDO's) recognizing the need from stakeholders (industry, regulators, civil society organizations, and academia) to address multifaceted issues related to emerging nanotechnologies. Today, there is a growing international transition for organizations originally focused on nanomaterials to focus on advanced materials and emerging materials.

*Are those standards organizations working on nanotechnology-specific standards the appropriate place to address advanced and emerging materials?*

**The Benefit of Utilizing the Experience of the existing nano SDO's.**

SDOs focused on nanotechnologies tend to have significant multidisciplinary participation and have experienced the challenges associated with standardization of a developing class of advanced materials (i.e., nanomaterials). However, concerns may be raised that advanced materials span further than "nanomaterials" and that even broader skillsets are required to appropriately address this issue. This, however, would be true for any existing group to address a broad area such as emerging/advanced materials.

<u>Existing Horizontal Committees and Multidisciplinary/Interdisciplinary Experience.</u> While many SDO Committees are narrowly focused on one specific application space with specific industrial stakeholders (e.g., paint and coating manufactures and users, or lawnmower technologies), some SDOs have been organized horizontally to facilitate commercialization of nanotechnologies across the broader spectrum of inclusive areas (paints, coatings, microelectronics, composites, regulatory needs etc.). These horizontal committees necessitate the participation of diverse disciplinary and interdisciplinary contributors and commensurate with this, address a wider range of activities spanning from terminology, health and safety, material specifications and characterization.

**Current activities within existing organizations:**

Within ISO TC229, Joint Working Group 1 on Terminology has formed a study group to consider the needs to develop consistent practices for advanced materials and Working Group 3 is also considering if it is appropriate to include some advanced materials within its purview. It is reasonable to believe that other SDO's are also considering issues pertaining to AM. WG3 has updated its "roadmap" to include advanced/emerging materials.

Beyond standards, the OECD Working Party on Manufactured Nanomaterial has discussed whether it should include AM in its activities. This could make sense for the WPMN as its members have the legal responsibility to provide oversight to materials generally within their respective delegations. The German delegation is hosting a series of three workshops to collect perspectives from interested stakeholders with two workshops completed so far.

**Where are we now?**

Over the last 15 years much has been learned about nanotechnologies and focused SDOs have been helpful for addressing complex nanomaterials integrating contributions from diverse international stakeholder groups. While it has always been understood that nanotechnologies were originally defined to encourage research and development of ultra-small systems arbitrarily limited to 1-100 nm, it is apparent today that this size-based definition may no longer be an appropriate umbrella for dealing with the spirit and challenges originally raised. Many parallel governmental, industrial, research and development, and regulatory bodies are transitioning from a focus on “nanomaterials” to other more complex emerging materials. In many discussions the terms “advanced materials” or “emerging materials technologies” are being used.

Currently, there is a growing recognition among some practitioners that size alone does not fully define the unique properties of a material nor the need to develop new terminology, characterization methods, health and safety standards, nor new material or product specifications. For example, within ISO TC 229 there have also been challenges regarding deciding when an item should be addressed within TC229 or within another ISO committee focused on the end use activity. Not all nanomaterials and not all nanotechnologies offer new challenges. As many nanotechnologies (or advanced materials in general) move from being ‘advanced and emerging’ to ‘established’, how should the standards be maintained and handled? For instance, should they simply be dealt with by the respective related vertical committee groups, e.g., Paints and coatings. Is the intent of Nanotechnology SDOs to address complex emerging technologies related only to nanotechnologies? Are the bounds of nanotechnology too limiting or sufficiently broad? While past efforts under the umbrella of nanotechnologies made useful and timely contributions to trade and commerce, future emerging technologies—though potentially related to nanotechnologies—may not have a clear home in the standardization world. Is this an area that the expertise in SDOs developing standards in nanotechnologies can address?

**Why use existing approaches for NM for AM:**

The issues that have been presented pertaining to nanomaterials and nanotechnology are the same as those pertaining to Advanced Materials and Emerging Material Technologies. For example:

*Terminology*

- What is an advanced material? What is an emerging material? Are these even the right terms to use? (e.g., should a new term be created or is there a better alternative)
- What are the terms pertaining to advanced materials that are ambiguous and that require clarification?

    - Consider "advanced materials" from the perspective of different industries or from different stake holders.
    - Consider different points in time.  When is an advance material not an advanced material?
- Are there terms that are used incorrectly and their use leads to confusion or erroneous conclusions?

*Metrology*

- What are the important properties regarding advanced materials? Emerging materials? For nanomaterials a fundamental property is size but for advanced materials there could be other distinguishing properties.
- Are there applicable methods to obtain measurement of these properties?
- Are the measurements mature enough for standardization?  If not, can they be further developed or does new metrology need to be developed?

*EHS*

- Do advanced materials and emerging materials potentially present new hazards?  Could these hazards be foreseen using the existing paradigm?
- What are the potential hazards and are their tools to evaluate them?
- Are the potential hazards sufficiently different that new standard methods are needed and that existing methods are not adequate?
- How do new intersections between societal use of advance materials or emerging materials present new challenges and considerations?

*Materials specification and applications*

- For many materials standardization is not desired as uniqueness provides a commercial advantage to the supplier.  Are there materials for which standardization would provide a commercial benefit to many manufacturers?
- Are there manufacturing methods that require standardization or for which there are commercial benefits?
- Are there any performance characteristics of advanced materials requiring standardization?

The list above is not complete but mirrors the issues addressed by ISO TC229 and other Nanotechnology SDOs.  The expertise to address these issues is already present in many SDOs making it more likely that the issues can be addressed efficiently without creating a new group.  It seems likely that other groups that have been addressing nanotechnology will also consider including advanced materials, including industry associations and the OECD WPMN.

**Why not:**

One argument would be that the "advanced and emerging materials" broadens the scope to infathomable limits.  But is this true?  Is there a meaningful way to focus work?  Another reason may be bandwidth.  There could be concerns that Nanotechnology SDOs already have enough work to do and the resources are limited.  However, considering advanced and emerging materials could bring in new resources and others see that TC229 and other SDOs could capitalize on to help address issues before they become concerns.

**The Benefit of Utilizing the Experience of a Horizontal Committee Structure and Multidisciplinary Nature:**

Existing SDO's have over 15 years of unique experience in proactively addressing standardization needs of new materials. Are these groups the appropriate places to address advanced materials and emerging technologies?  Will remaining in the status quo "nanotechnologies" justify a horizontal structure in the future?

**Questions for sharing before the meeting**

- Do <u>you</u> have a personal definition of *advanced material*? Related emerging material technologies?
- Does <u>your organization</u> have a definition of *advanced material*? Emerging material technologies?
- Are you aware of topics pertaining to advanced materials and related emerging material technologies that are unique from nanotechnology?
- Are you aware of organizations that are addressing issues pertaining to advanced materials and related emerging technologies? Who are they?
- Are you aware of regulatory/government organizations who are addressing advanced materials and related emerging technologies? Which ones?
- What developments in advanced materials and related emerging technologies are you seeing that will provide significant societal benefits?
- What developments in advanced materials and related emerging technologies are you seeing that have created concerns?
- Please provide specific examples of advanced materials and related emerging technologies?
- What applications will benefit the most from advanced materials and related emerging technologies?
- What do you think of the thought starter recommendation to include advanced materials and related emerging technologies? Did this thought starter recommendation miss anything?
- Early in their life cycle, materials may be considered to be *advanced* but eventually the properties become routine and new *advanced* materials come along. Should nano SDO's consider modifying their scopes to cover emerging materials/technologies to provide a consistent structure to evaluate new materials and technologies?

# Annex C:  Workshop Presentations

# Exposure and Risk Assessment Approaches for Emerging Consumer Technologies and Materials

Treye Thomas, Ph.D.
Program Manager
Chemicals, Nanotechnology and Emerging Materials
Office of Hazard Identification and Reduction

# U.S. Consumer Product Safety Commission

CPSC is a federal government agency charged with protecting the public from unreasonable risks of injury or death associated with the use of over 15,000 types of consumer products under the agency's jurisdiction.

**$1 Trillion**

Deaths, injuries, and property damage from consumer product incidents cost the nation more than $1 trillion annually.

**CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical, biological, or mechanical hazard.**

**CPSC's work to improve the safety of consumer products - such as toys, cribs, power tools, cigarette lighters, textiles, and household chemicals - contributed to a decline in the rate of deaths and injuries associated with consumer products over the past 40 years.**

# Emerging Hazards and Trends

Emerging and future consumer products and technologies identified in this report include:

- **3D Printers and the printed products;**
- **Internet home-based smart technologies (IOT);**
- **Wearable products and technologies;**
- **New materials, including nanomaterials;**
- **Virtual reality (VR) and augmented reality (AR) games;**
- Robotics, including robotic products to assist older adults


CONSUMER PRODUCT SAFETY COMMISSION • UNITED STATES OF AMERICA •

**Staff Report**

Potential Hazards Associated with Emerging and Future Technologies

January 18, 2017

*The views expressed in this report are those of the CPSC staff and they have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.*

https://www.cpsc.gov/s3fs-public/Report%20on%20Emerging%20Consumer%20Products%20and%20Technologies_FINAL.pdf

# ADVANCED MATERIALS
## NIOSH PERSPECTIVE

ANSI-NSP Workshop
August 19-20, 2020

Chuck Geraci, PhD, CIH

Associate Director for Emerging Technologies

Gary Roth, PhD

Health Scientist, Emerging Technologies

# TECHNOLOGIES THAT IMPACT THE WORKPLACE

- Nanotechnology
- Advanced Materials
- Biotechnology
- Additive Manufacturing/3D Printing
- Digitalization and advanced computing
- Artificial Intelligence, Machine Learning (VR, AR)
- Sensing Technology
- Modeling and Simulation
- Robotics

Drawn from several forecasting reports.

# TECHNOLOGIES THAT IMPACT THE WORKPLACE

- Nanotechnology
- Advanced Materials
- Biotechnology
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- Digitalization and advanced computing
- Artificial Intelligence, Machine Learning (VR, AR)
- Sensing Technology
- Modeling and Simulation
- Robotics

Advanced Material Component

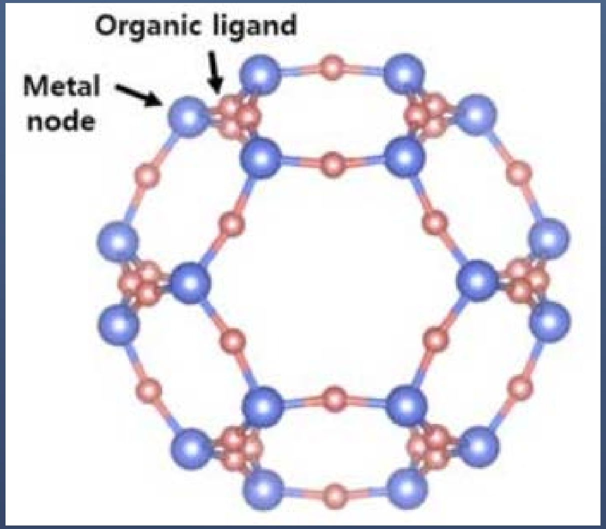
Drawn from several forecasting reports.

# ADVANCED MATERIALS

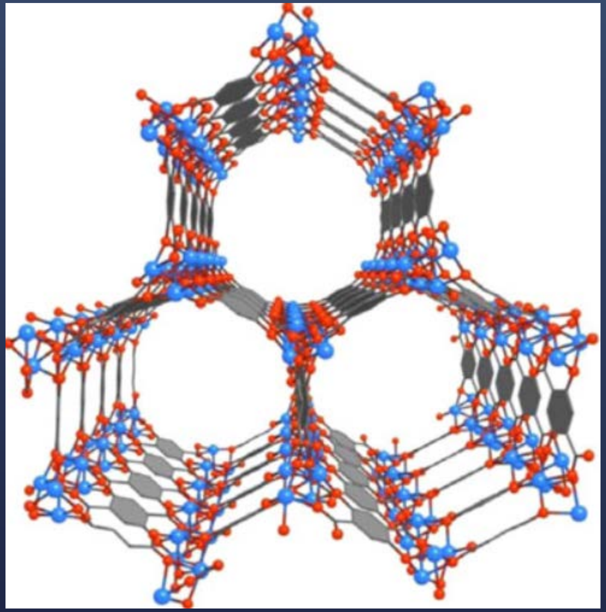
- Materials designed with a specific functionality or application in mind
- Generally more active
- Impart new or improved properties
- Functional textiles
- Biomaterials

Does more ‘active’ = higher hazard?

# Examples of Advanced Materials




Metal Organic Frameworks (MOF)



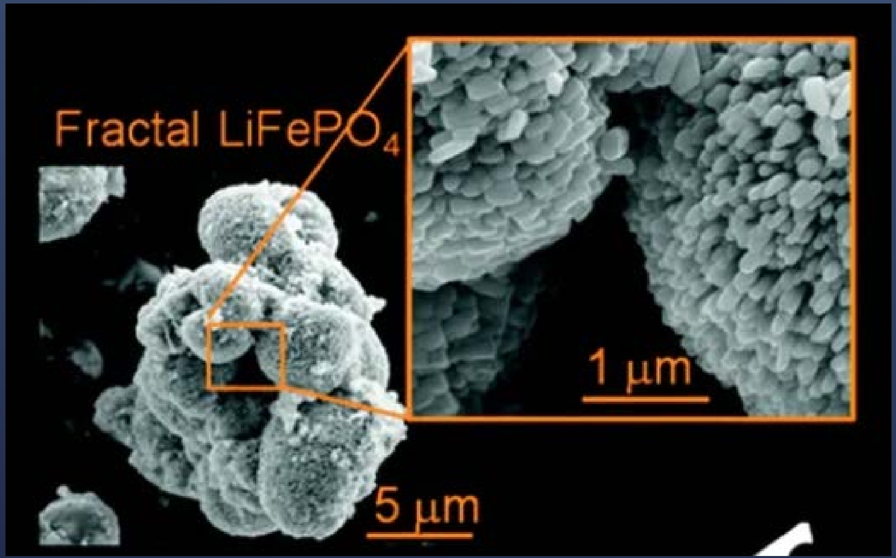
Cage like structures
Large internal and external surface area
Reactive
Manufactured as fine powders
Formed into solids for applications

Applications
3D Printing 'ink'
Gas storage
Drug delivery
Sensors
Nutrient detection and delivery

## Examples of Advanced Materials

The quest for a better Li Ion battery through more efficient electrode materials

Carbon/$LiFePO_4$ material research. "Reducing the size of the particles to create morphologies which could provide a path for better ion diffusion'




Caban-Huertas, Scientific Reports, 2016

If manufactured and processed in high volumes, would this material require special handling?

# Applying Current EHS Knowledge

Nanotechnology

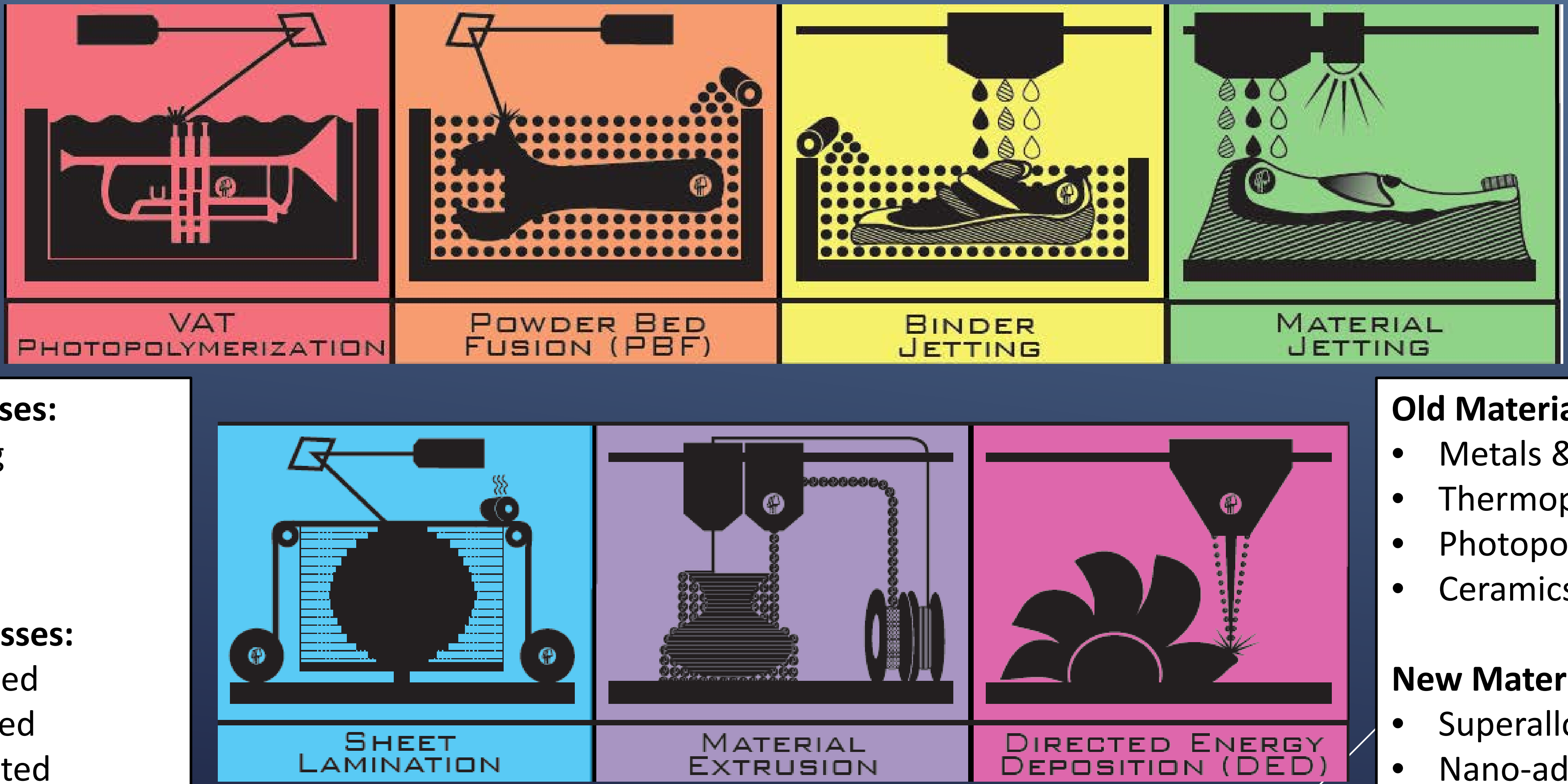
Advanced Materials

Advanced Manufacturing

# ADVANCED MATERIALS IN MANUFACTURING


**Some processes and some products.**

# Additive Manufacturing and 3D Printing
# Old & New Processes and Materials




**Old Processes:**
- Welding
- Curing
- Printing

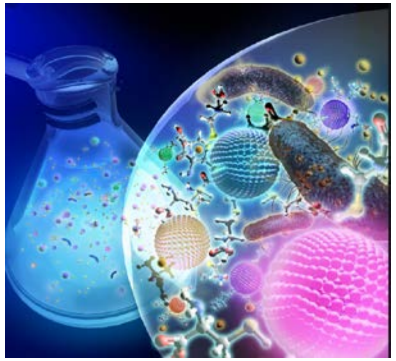
**New Processes:**
- Controlled
- Combined
- Automated

**Old Materials:**
- Metals & Alloys
- Thermoplastics
- Photopolymers
- Ceramics

**New Materials:**
- Superalloys
- Nano-additives

**Hazards resemble those of past materials and processes, but in new combinations and contexts.**

# Bio-Based Manufacturing



## Impact on Workers, Environment, and Consumers?

Synthetic Biology
-DNA Synthesis
-DNA Editing

→

New Organisms
New genetic material

→

Advanced Biotechnology
Manufacturing Processes

New Bio-based Products
Improved form of old products

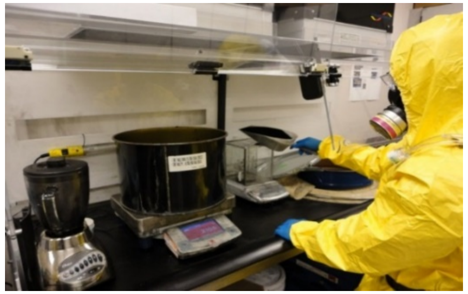
'Old' products a new way
New products

Will using Biology as a manufacturing technology create unanticipated hazards for workers and consumers?

Can existing biosafety, chemical safety, and other frameworks be used to achieve safe biology-based manufacturing? If not, what do we need to develop?

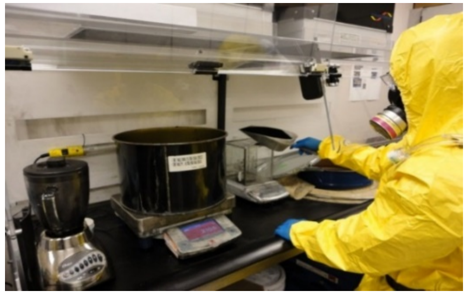
# NIOSH Nanotechnology Field Team

- Over 100 visits to 65 nanotechnology sites
- 19 visits to 11 additive manufacturing sites
- Use existing methods to evaluate processes & exposures
- Provide guidance and recommendations to partners
- Fill knowledge gaps on real-world technologies, uses, and exposures
- Always seeking more partnerships and collaborations!



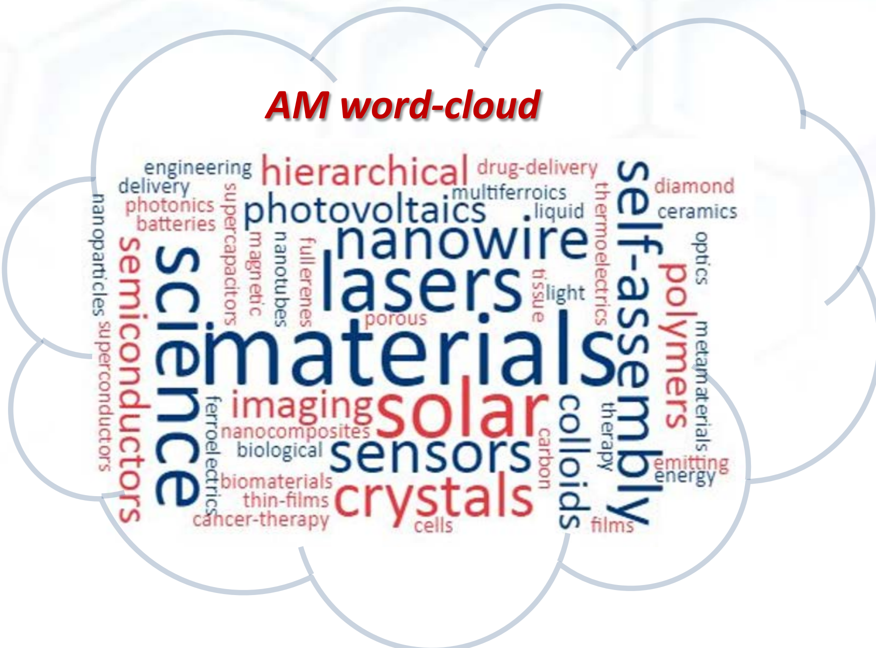
# NIOSH ~~Nanotechnology~~ Advanced Materials and Manufacturing Field Team (AMMFT)

- Over 100 visits to 65 nanotechnology sites
- 19 visits to 11 additive manufacturing sites
- Use existing methods to evaluate processes & exposures
- Provide guidance and recommendations to partners
- Fill knowledge gaps on real-world technologies, uses, and exposures
- Always seeking more partnerships and collaborations!

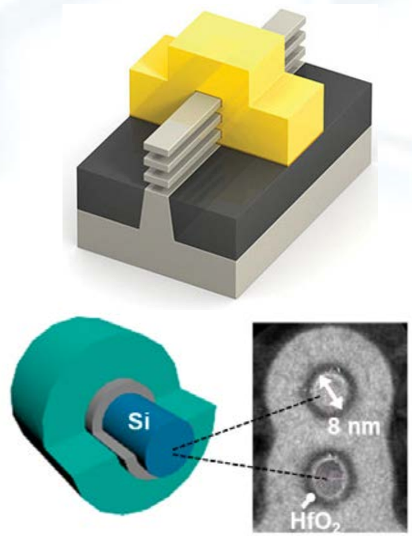


# Advanced Materials (**AM**)

- **AM** exhibit *novel or enhanced properties* (electronic, optical, magnetic, mechanical…) that improve performance over conventional products and processes, e.g.:
  - ultra-thin vs. conventional silicon in transistors
  - carbon nanotubes for quantum optics

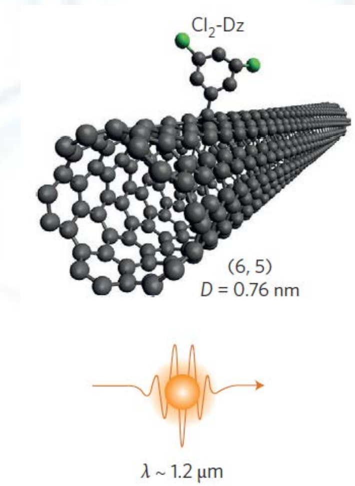



**Stacked nanowire FET**




*Appl. Sci.* **2020**, *10*, *2979*

**Emission from SWCNT**

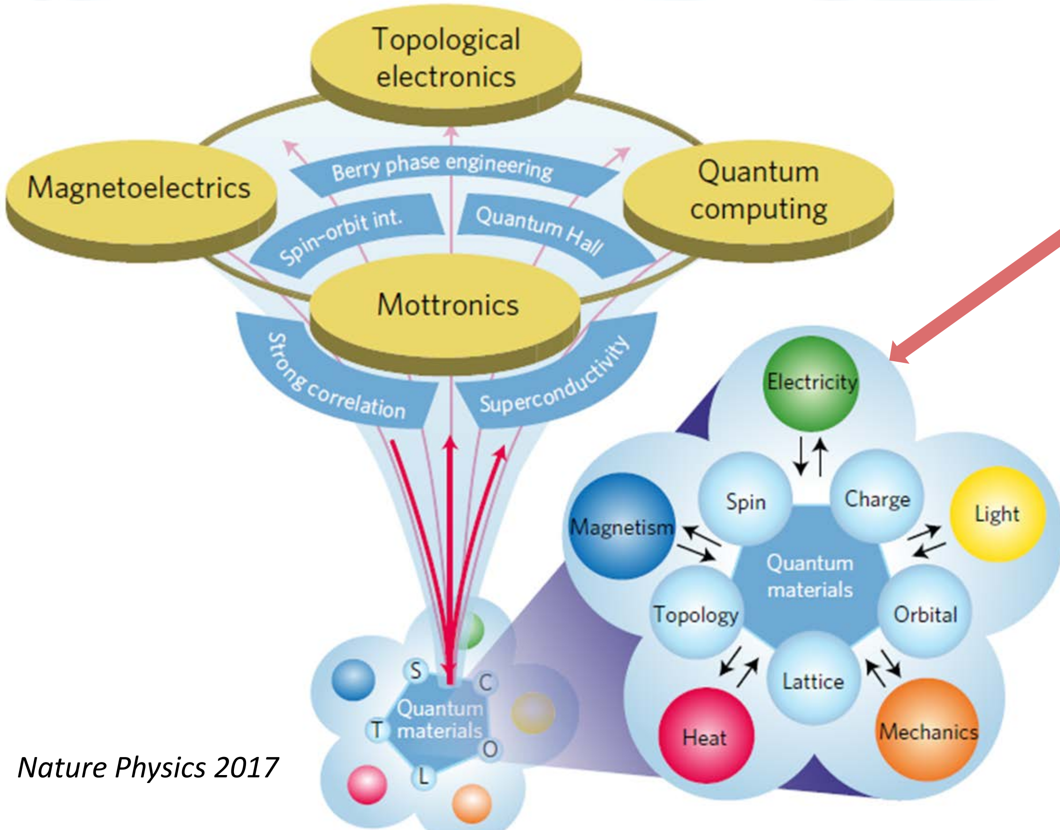



*Nature Photonics* **2017**, *11*, *535*

Needs for **AM** standardization:

- Establishing "Structure – Property – Performance" relationship
- Standardization of emerging technological processes
- Establishing EHS standards
- Support National initiatives: a) Quantum Information Science, b) CHIPs for America (microelectronics)

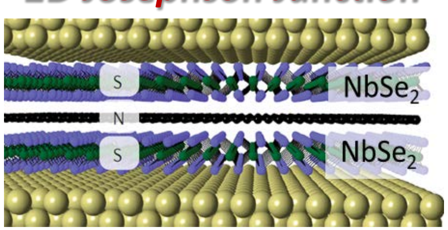
# Quantum Materials (**QM**)



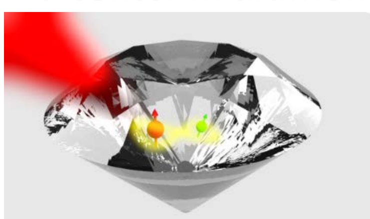

*Nature Physics 2017*


**QM** – materials in which quantum phenomena (topology, spin-orbit, confinement, symmetry) manifest over a wide range of energies and length-scales

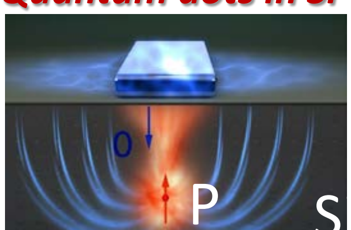
***2D Josephson Junction***



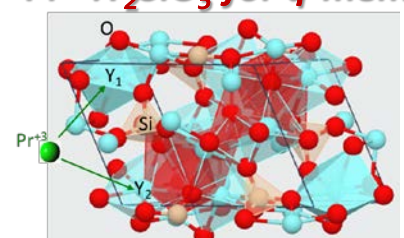

***N-V center in diamond***



***Quantum dots in Si***




***$Pr^{+3}$:$Y_2SiO_5$ for q-memory***

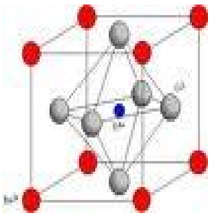


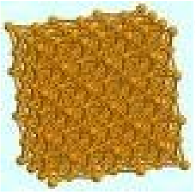
# Scope of Advanced Materials

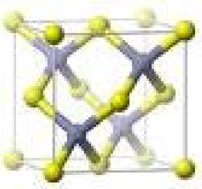
***Condensed phases, including***

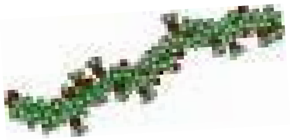
Ceramics
Metals
Polymers
Composites

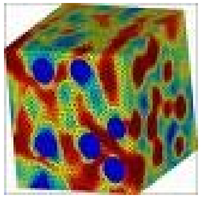
Semiconductors
Biomaterials
Fluids

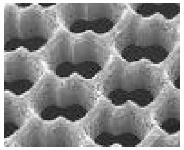






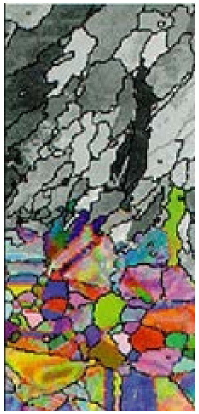


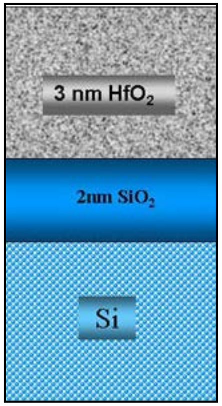


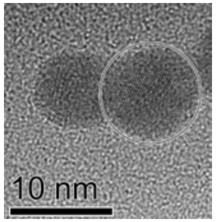


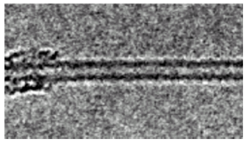
***in all forms, including***

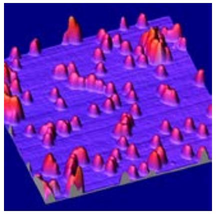
Bulk
Multilayer
Tube, rod
Particulate







***at all length scales***

nanoscale ⟶ microscale ⟶ mesoscale ⟶ macroscale

# ADVANCED MATERIALS

## *-A Perspective from Industry-*

**Scott. C. Brown**

The Chemours Company

Disclaimer: The opinions expressed are those of the presenter and do not necessarily reflect those of the Chemours Company.

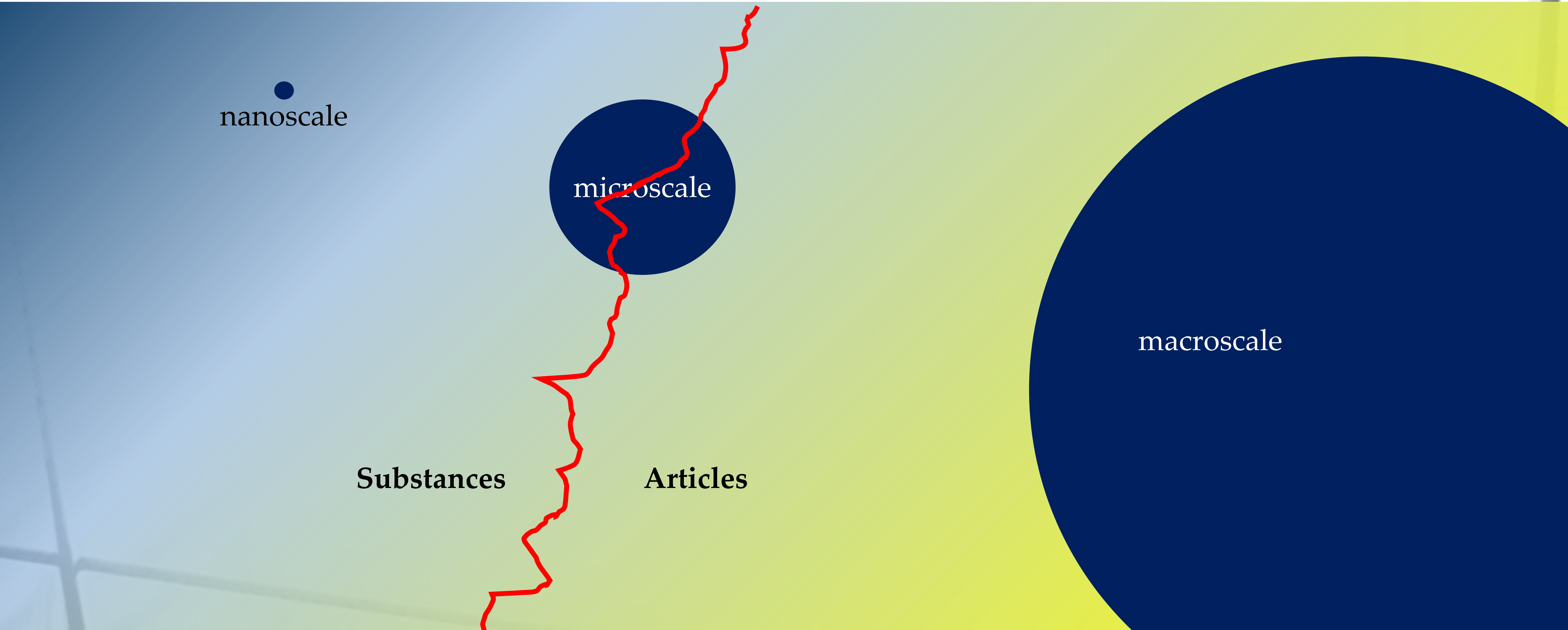
# Advanced Materials

- A descriptor for materials with improved properties over those existing or commonly used. They can be:

- Light-Weight Alloys
- Unique & Novel Nanomaterials
- Common Materials in New Applications
- Shape-Memory Materials
- Active Coatings
- Safer-by-Design Substances
- Materials from Advanced Processing
- Smart Materials
- Atomically-Precise Materials
- Stimuli Responsive Materials
- Active Materials
- Self-healing Materials
- Material Structure Enhanced Materials

**A wide range of substances… Almost Endless Possibilities…**

# ‘Advanced Materials’ are not defined by size



# ‘Advanced Materials’ change with time…

PAST

PRESENT

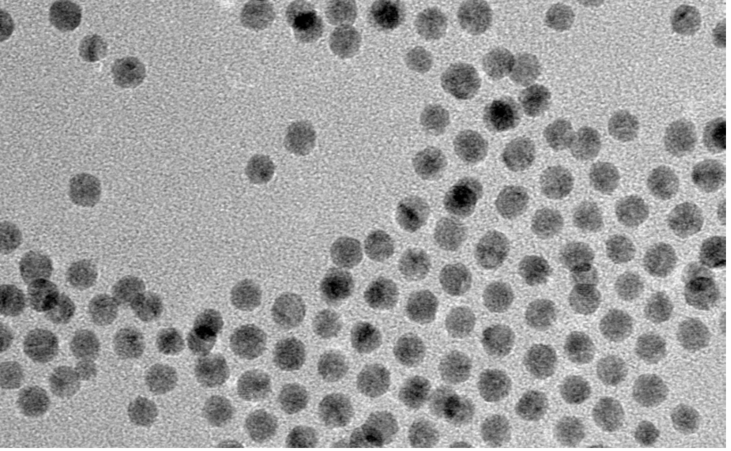
FUTURE

Steel

e.g., Graphene Composites

??????

What was ‘advanced’ is no longer ‘advanced’ …



# ‘Advanced Materials’ are subject to interpretation

| Microelectronics | Paints & Coatings | Construction |
| --- | --- | --- |
| Common Use,<br>Benchmark Performance,<br>**Not ‘Advanced’** | New Use,<br>In kind Performance,<br>**Not ‘Advanced’** | New Use,<br>Enhanced Performance,<br>**‘Advanced’** |

**Improvements in performance depend on a given application and perspective….**

**All nanomaterials are not ‘Advanced Materials’**

(But it depends on frame of reference and time…)

**Not all ‘Advanced Materials’ are ‘different’**

(But it depends on frame of reference and time…)

**➔General need for clarity and an opportunity for standards development**

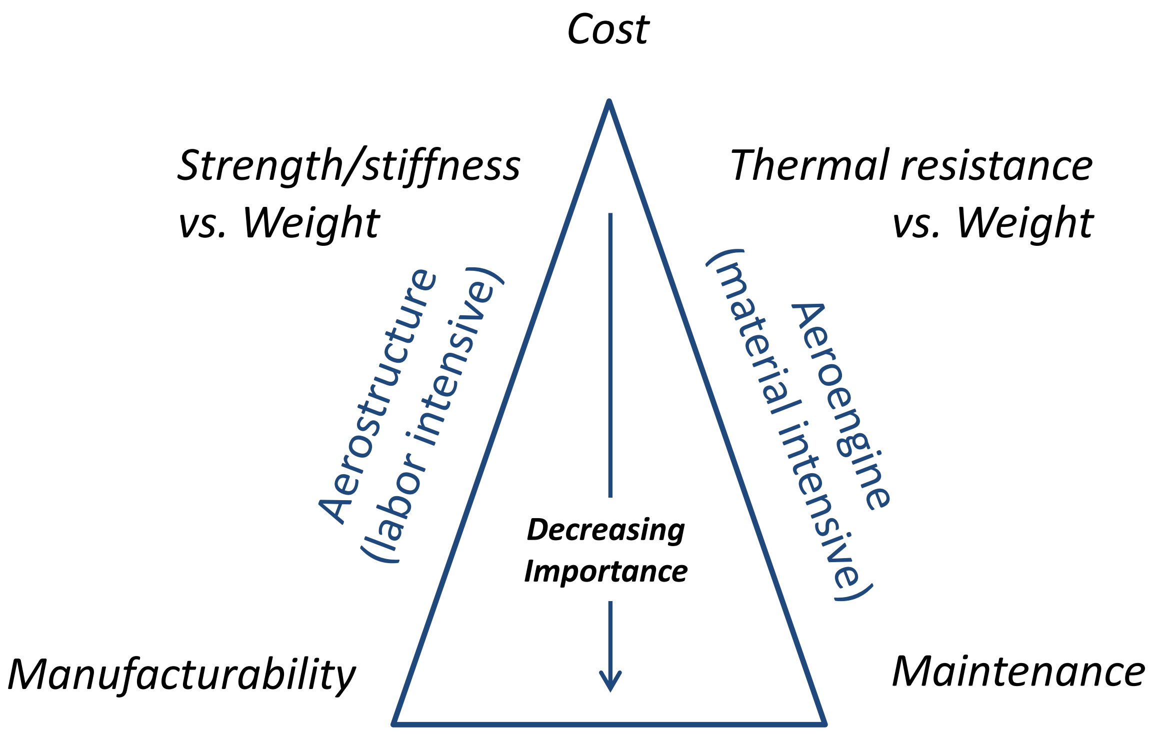
# Some Challenges & Opportunities

- **How do you "standardize" a moving target (e.g., evolving technologies)?**
  - ➔ Relates to "unique and novel" discussions in early nanotechnology standardization…
  - ➔ Do we identify "normal" instead? (where needed)
  - ➔ How do we use this to encourage safe, sustainable innovation?

- **Efforts in this area will require broader outreach across communities and "normalization" of concepts and terminology.**
  - Nanotechnology committees may be ideal starting points but broader participation and cooperation will be necessary
  - Strong overlap with the "meat and potatoes" of various industries and other standardization interests – how do you avoid conflicting scopes? How do you synergistically augment activities?
  - Narrowing down to what is important and meaningful will be critical. ➔ Learnings from nanotechnology.

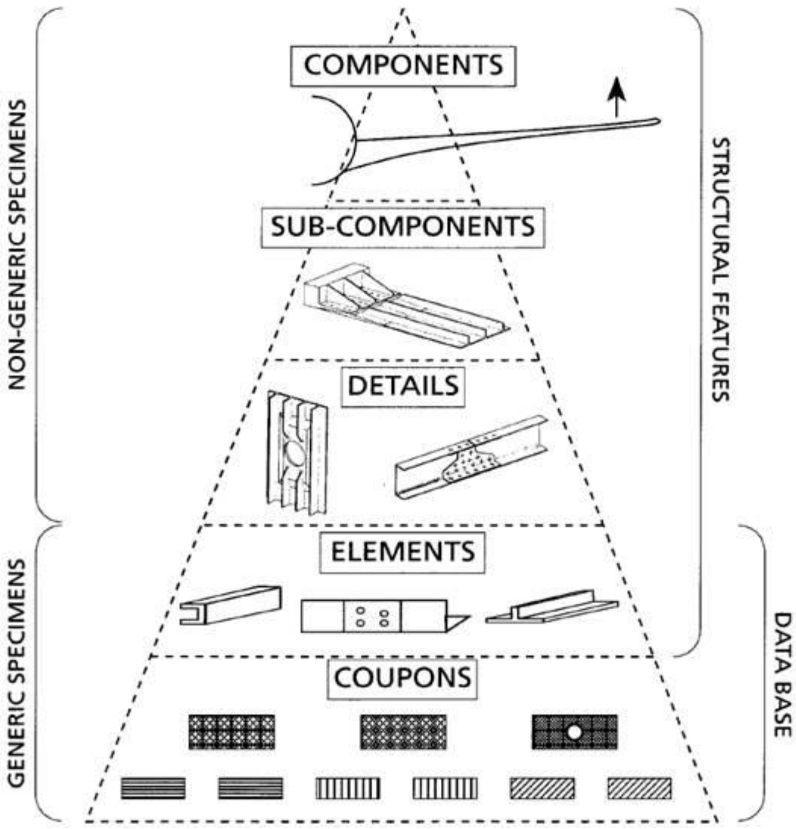
# Aerostructure and aeroengine design objectives drive their respective material usage

Aerospace Design Considerations



# FAA/EASA rigorous certification process helps to ensure aircraft safety

Aircraft Design Substantiation




- Certification is process of substantiating both aircraft design and production
- Engineering proves structure can withstand anticipated static and dynamic loads
- Testing begins with material samples to identify basic material properties
- In certain cases, full-scale testing is required – expensive both in time and money

Role of Standards

# SAE is one such Standards Development Organization (SDO) responsible for driving aeromaterial advancement

SAE Aerospace Material Specifications (AMS) Timeline

**SAE AMS:**

First AMS published

$1000^{th}$ AMS published

Perry Reform & Transfer of DoD Specs to SDOs

FAA memo for additive mfg

1925 | 1950 | 1975 | 2000 | 2025

**Aero materials:**

Aluminum

Superalloys

Titanium

Thermoset composites

Metal add mfg

Thermo-plastics & Ceramics

*Advanced Materials: Lessons from Nano*


Mark R. Wiesner

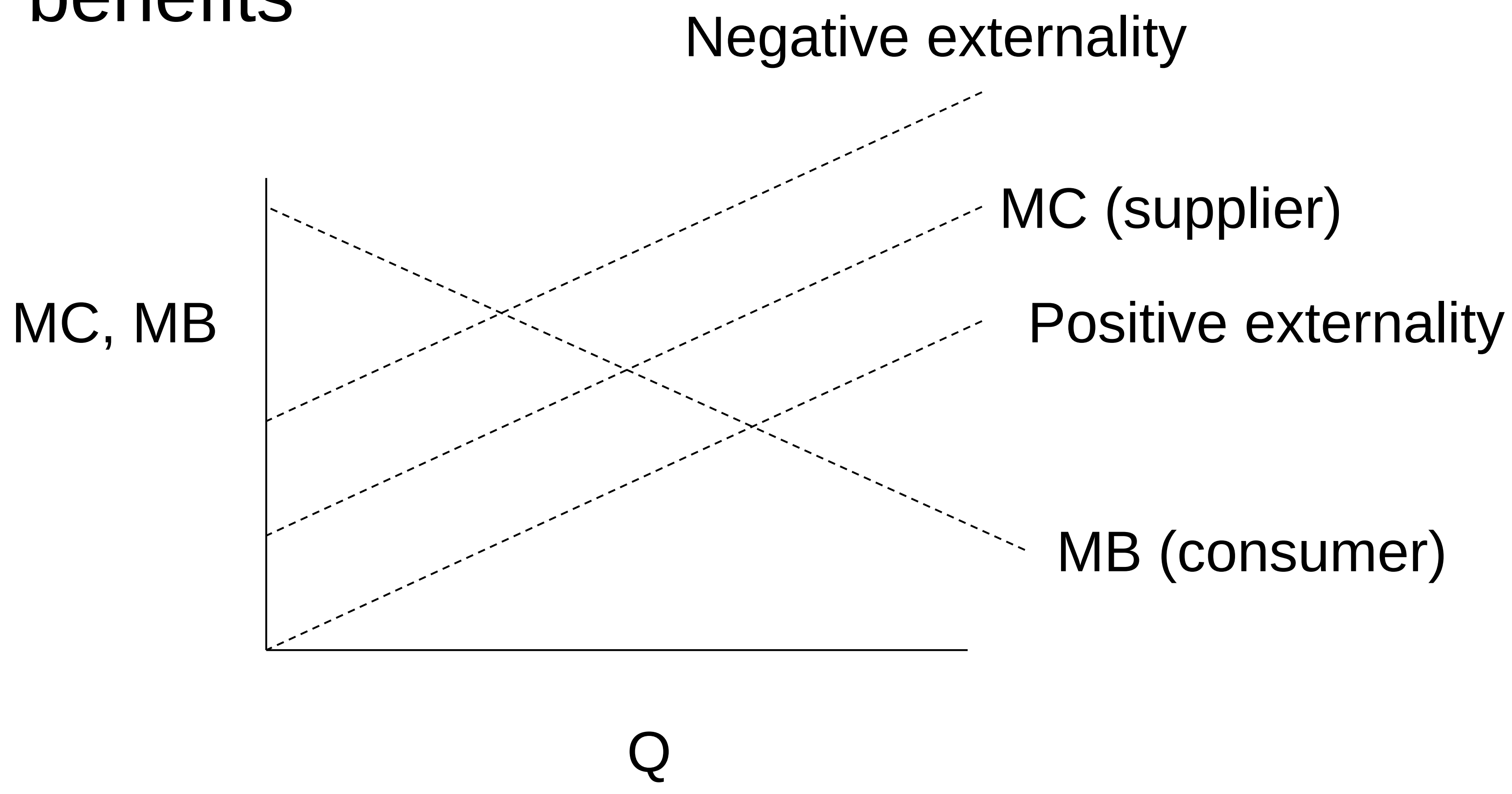
Director

wiesner@duke.edu

CEINT

Center for the Environmental Implications of NanoTechnology

# When externalities occur, the price does not capture all costs or benefits



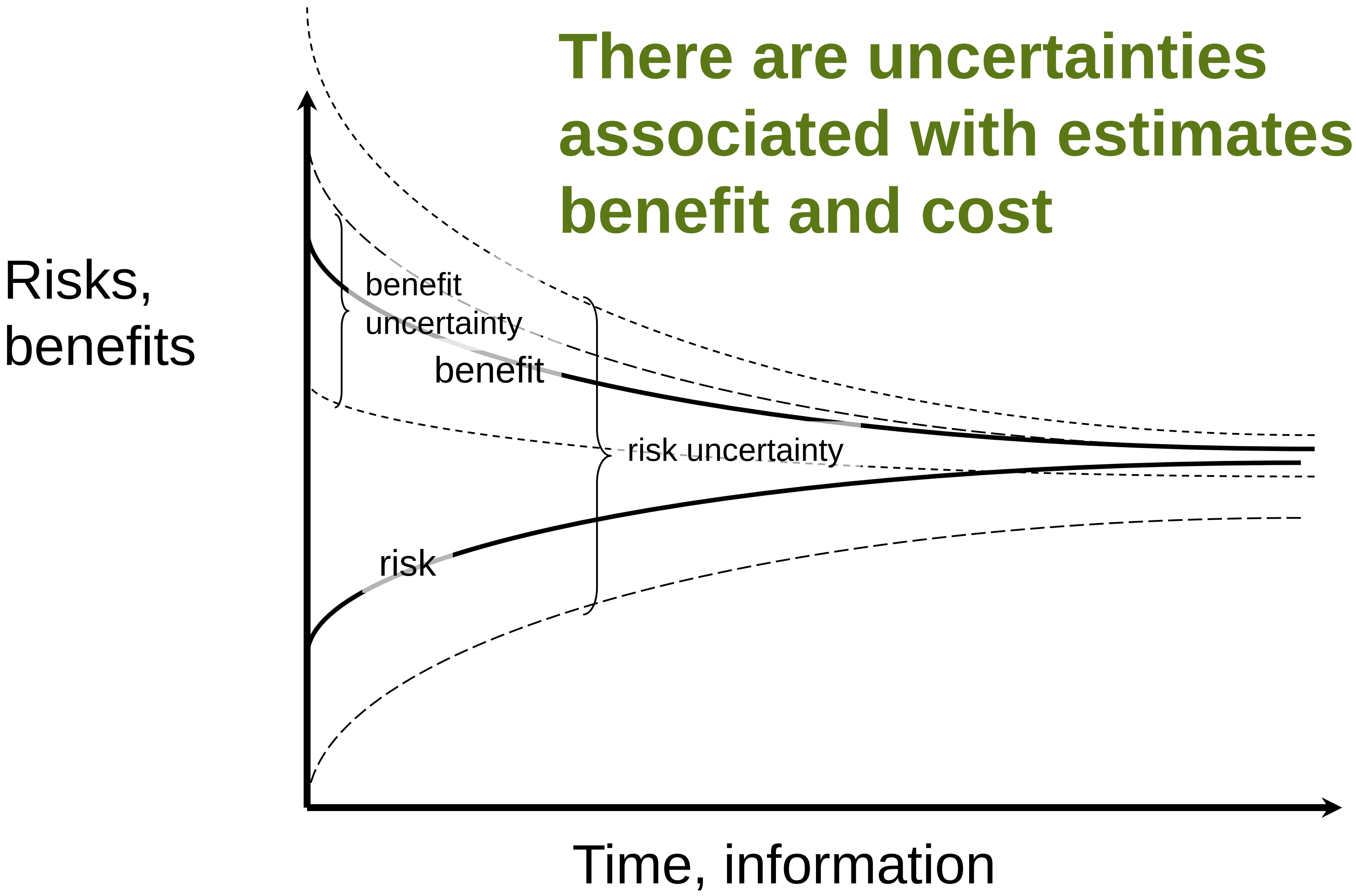

Producers, consumers, workers, general public as stakeholders

# EHS research is a public good

**A public good** is a good that individuals cannot be effectively excluded from use and where use by one individual does not reduce availability to others.

# Who are the consumers of this good?

# There are uncertainties associated with estimates of benefit and cost





Contents lists available at ScienceDirect
Comptes Rendus Physique
www.sciencedirect.com


A risk forecasting process for nanostructured materials, and nanomanufacturing

*Un processus de prévision des risques pour les nanomatériaux et la nanofabrication*


Mark R. Wiesner [a,c,d,*], Jean-Yves Bottero [a,b,c,d]

# Reducing Uncertainty Through Data Sharing:

## Example- The NanoInformatics Knowledge Commons

Biomax INFORMATICS

CEINT

eNM eNanoMapper

Serenade

NIKC

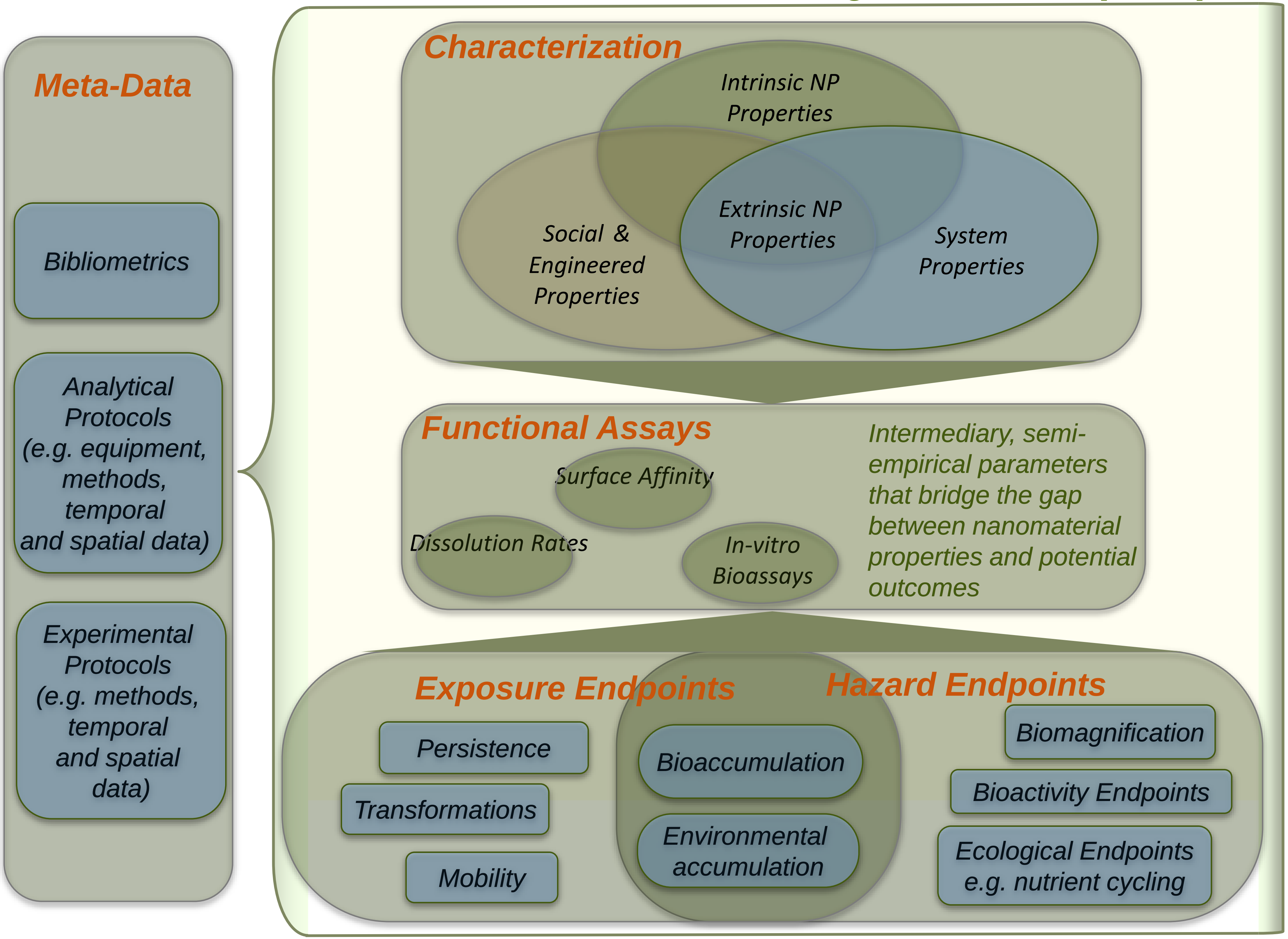
NanoFASE

NanoCommons
Nano-Knowledge Community

iCEINT

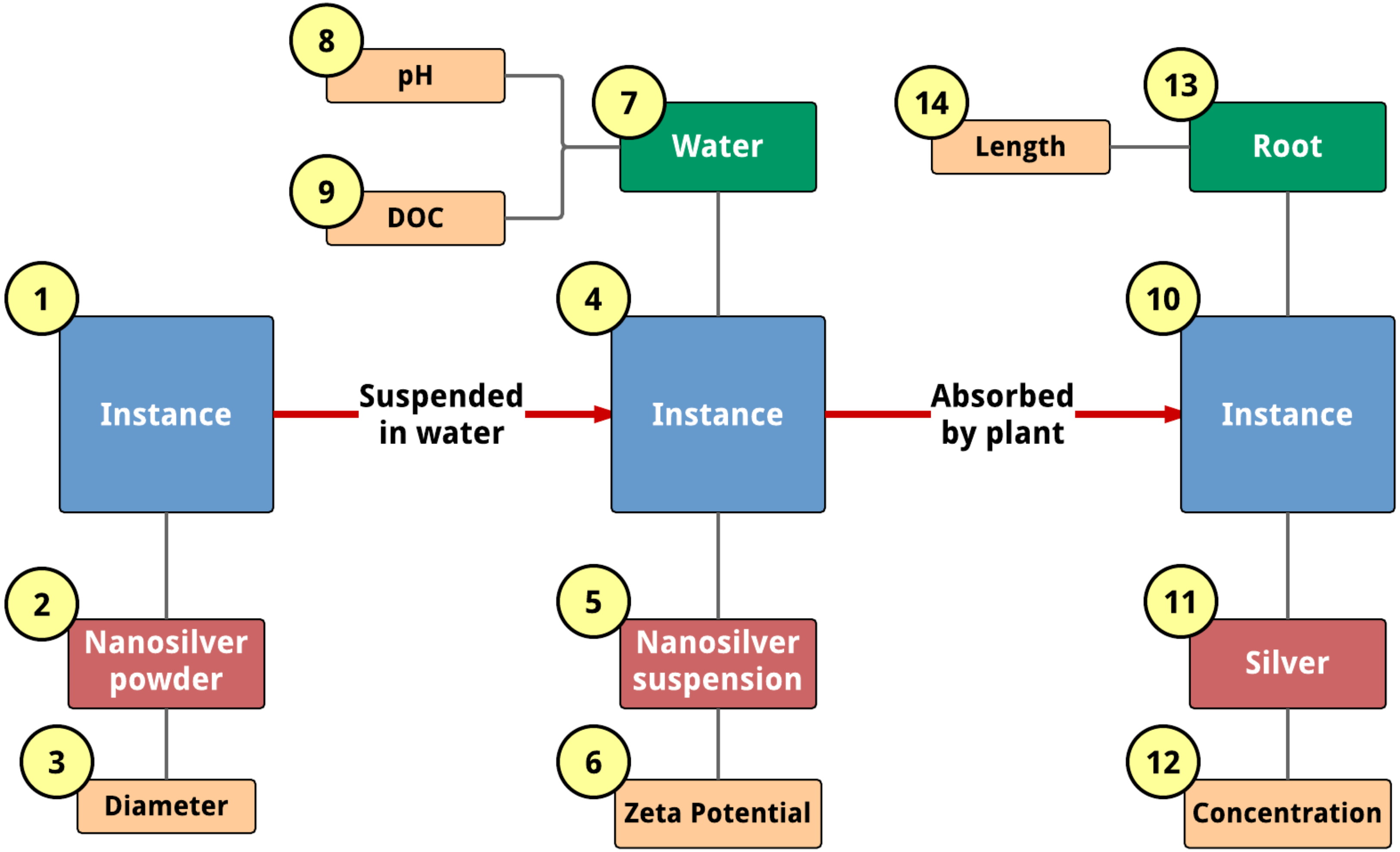
us eu
bridging nanoEHS research efforts

# Data in the CEINT NanoInformatics Knowledge Commons (NIKC)



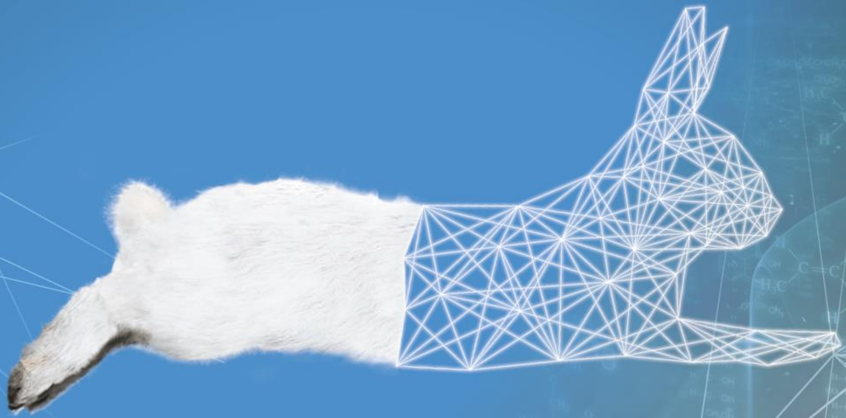
# Populating Measurement Table

## Accumulation of Nanosilver by Plant



# ANSI Nanotechnology Standards Panel (ANSI-NSP) workshop: Advanced Materials
# August 19-20, 2020

Monita Sharma, Ph.D.
PETA International Science Consortium Ltd.
MonitaS@PISCLtd.org.uk
www.PISCLtd.org.uk



PETA INTERNATIONAL
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FUNDING

TRAINING

WORKSHOPS
AND WEBINARS

PUBLICATIONS
AND PRESENTATIONS

RETROSPECTIVE
REVIEWS

# Goals of the Workshop:

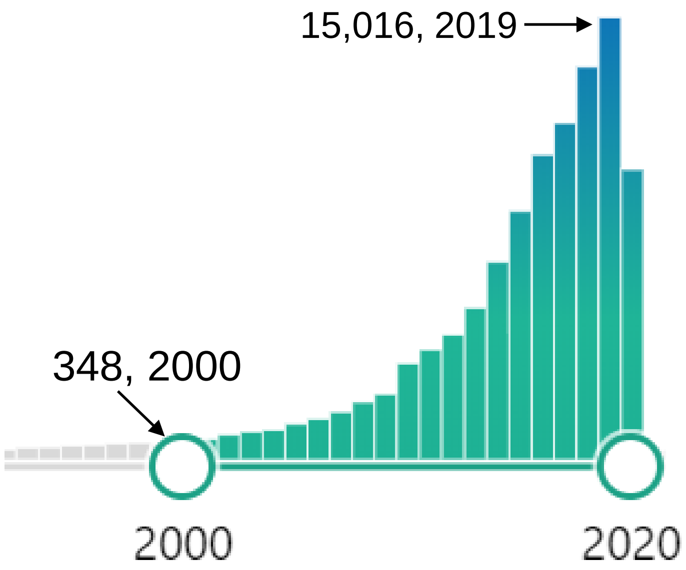
- Should we use existing nanotechnology standards bodies to address Advanced Materials?

- How can we do better at identifying the gaps and the needs relative to Advanced Materials Standards, and how do we prioritize topic areas?

# Advanced materials

Pubmed search (July 30, 2020)

| Query | Results |
|---|---|
| Advanced materials | 91, 403 |




Journals that cover different types of advanced materials


https://onlinelibrary.wiley.com

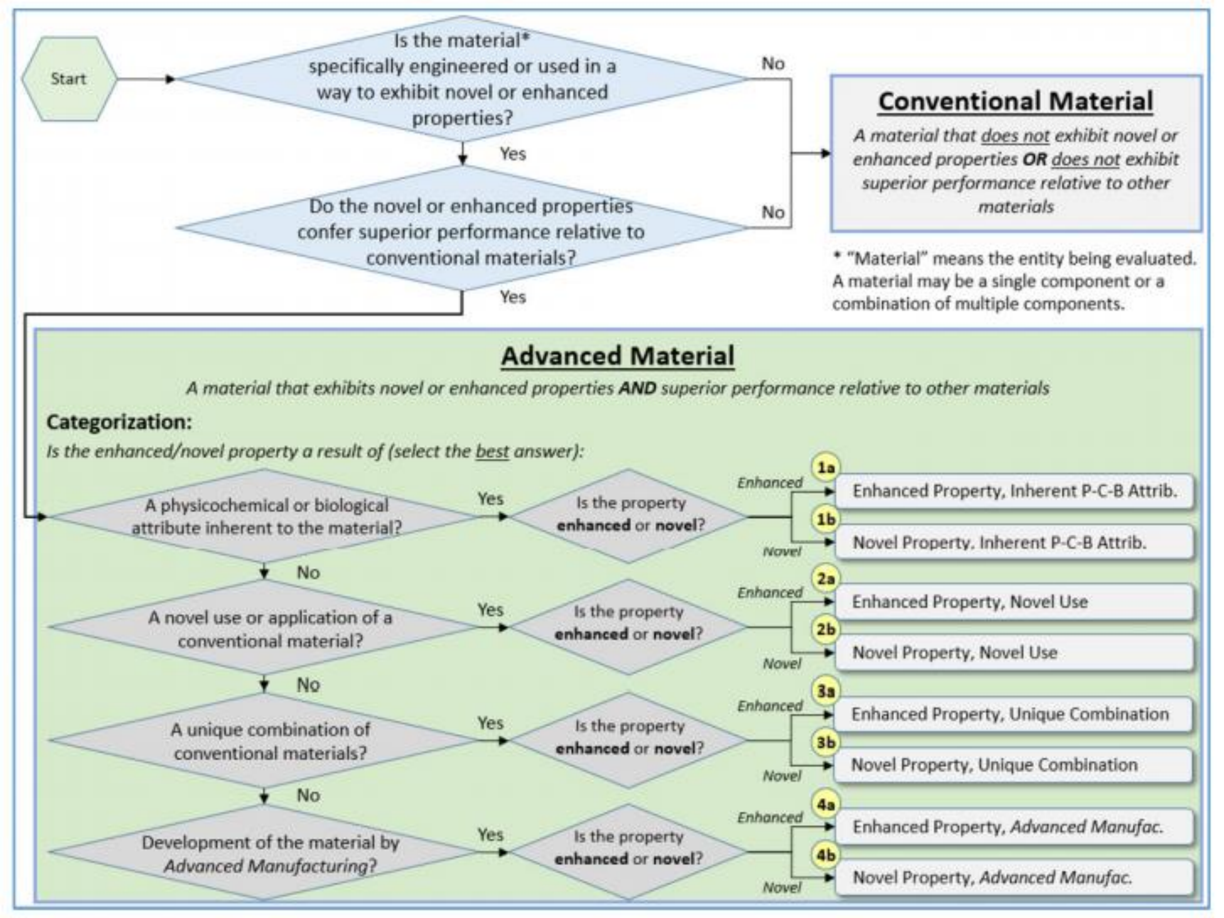
*Advanced materials – **Lighter, stronger and more sustainable**.* https://www.ayming.co.uk/

*Advanced materials involves the selection of the **optimum materials** and development of analytical methodologies to be used to ensure **robust designs**, whether they are for military systems or commercial products.*
https://www.quanterion.com/solutions/advanced-materials/

*Among the latest generation of advanced materials, those bearing the suffixes **“nano”, “bio”, “micro” and “smart”** are the key players.* https://seng.ust.hk/

# *Advanced materials* (AdMs):

Novel materials with unique or enhanced properties relative to conventional materials [Kennedy et al., 2019]



# Goals of the Workshop:

Should we use existing nanotechnology standards bodies to address Advanced Materials?

How can we do better at identifying the gaps and the needs relative to Advanced Materials Standards, and how do we prioritize topic areas?

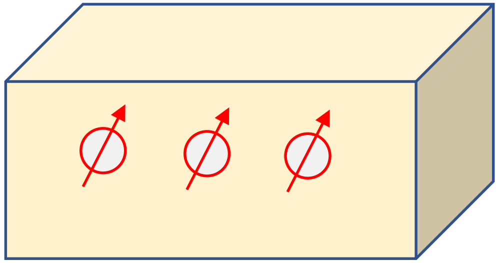
# Thank you!

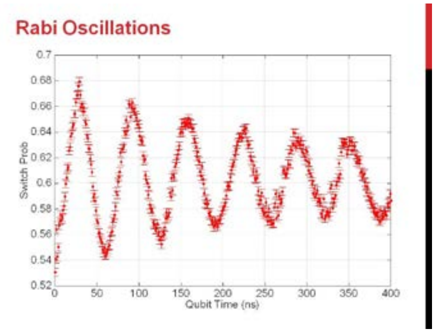
Monita Sharma, Ph.D.
PETA International Science Consortium Ltd.
MonitaS@PISCLtd.org.uk
www.PISCLtd.org.uk
@PISCLtd

**What makes an "Advanced Material" advanced?**

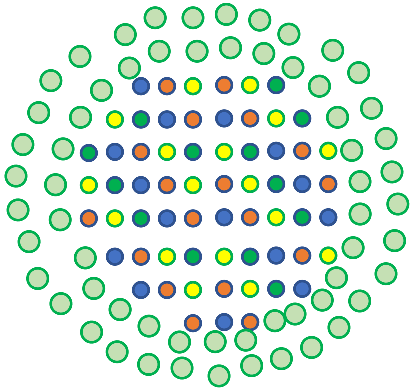
Is it *time ? (new = advanced?)*


Is it the resulting properties ?






Is it the chemical and physical microstructure ?



# What makes an "Advanced Material" advanced?

## ADVANCED MATERIALS: INFORMATION AND ANALYSIS NEEDS

T. Randall Curlee
Sujit Das
Russell Lee
David Trumble

Energy Division
Oak Ridge National Laboratory
Oak Ridge, Tennessee 37831-6205

Date Published: September 1990

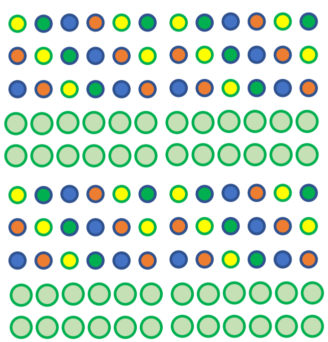
Advanced materials are those developed over the past 30 years or so, and being developed at present, that exhibit greater strength, higher strength density ratios, greater hardness, and/or one or more superior thermal, electrical, optical, or chemical properties when compared with traditional materials. Advanced ceramics, metals, and polymers, including composites of these, offer the promise of decreased energy consumption, better performance at lower cost, and less dependence on imports of strategic and critical materials. (page 5).

# What makes an "advanced material" unique?

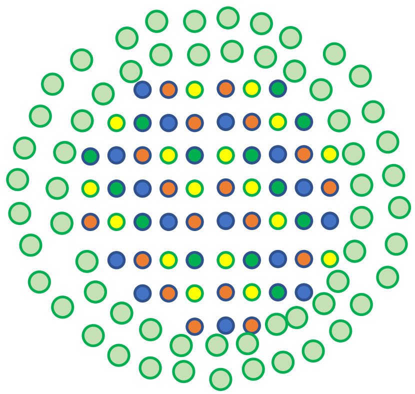
Internal structures (composition, structure) that might be "nano" even if the end product  does not fit the official "nano" designation

Examples:

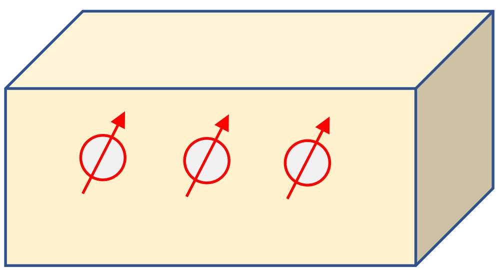
- Core-shell materials
- Compositionally graded structures
- Heterostructures



Superlattices



Core-shell >nano?



Quantum defects
(Nv, SiV, etc. centers)

Micro/Nanoelectronics
Optics/photonics

Energy Storage
(LIBs, supercaps, solar)

Quantum technologies

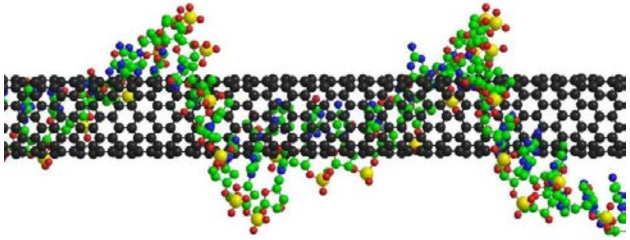
# My own perspective…

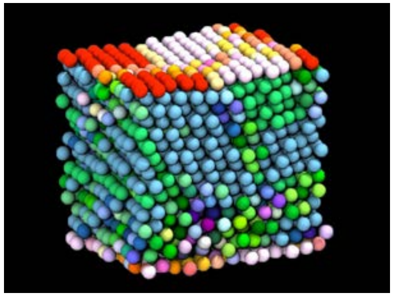
“Nano” was based almost entirely on *size* as the dominant/unique factor controlling materials properties at small length scales, and it was implict that small length scales brought unique unique chemical, physical, environmental helath and safety aspects.

Emerging industrial materials are more frequently using complex chemical compositions /chemical structuring along with physical nanostructuring.

There is a gap in understanding materials in which the chemical and physical structures together lead to emergent new properties.

- Amorphous materials
- Compositionally disordered materials (e.g., $LiNi_xMn_yCo_{1-x-y}O_2$) LIB cathodes
- Emergent compositions (silicenes, phosphores, 2-D materials/alloys
- Computational prediction of properties of non-crystalline / complex materials





https://cbe.princeton.edu/research/theory-and-simulation

# OECD – GENERAL VIEWS ON ADVANCED MATERIALS

**ANSI – Workshop on Advanced Materials**
**19-20 August 2020**

Mar Gonzalez
EHS Division
Environment Directorate

# OECD’s Chemicals Programme

**Countries work** together to develop and co-ordinate activities related to the safety of chemicals (including manufactured nanomaterials), pesticides and biocides and products of modern biotechnology.

The main objectives of the programme are to protect human health and the environment by assisting countries to

a) **anticipate**, **identify** and prevent or manage the risks of chemicals
b) ensure efficiencies and optimal use of resources for governments and industry through **harmonisation** of policies and instruments and
c) by creating mechanisms for **sharing work** in areas of mutual interest.

# OECD Chemical's Programme of Work and AM

- No definition of Advanced Materials
- No need for a new Programme of Work
- Knowledge on Advanced Materials / New Approaches
- Monitoring activities

Session on International Perspectives on Advanced Materials

# Advanced Materials. Any new issues for safety assessment?


## Kirsten Rasmussen, JRC


ANSI Nanotechnology Standards Panel. Advanced Materials,
19-20 Aug 2020

# Advanced Materials. Any new issues for safety assessment??

Personal view (disclaimer)

- *The Joint Research Centre (JRC) in the European Commission*
- *Chemicals legislation and advanced materials*
- *Next step: JRC and DG RTD* virtual "Workshop on Safe and Sustainable Smart Nanomaterials", 9-10 Sep. 2020*

**DG RTD: Directorate General Research and Innovation*

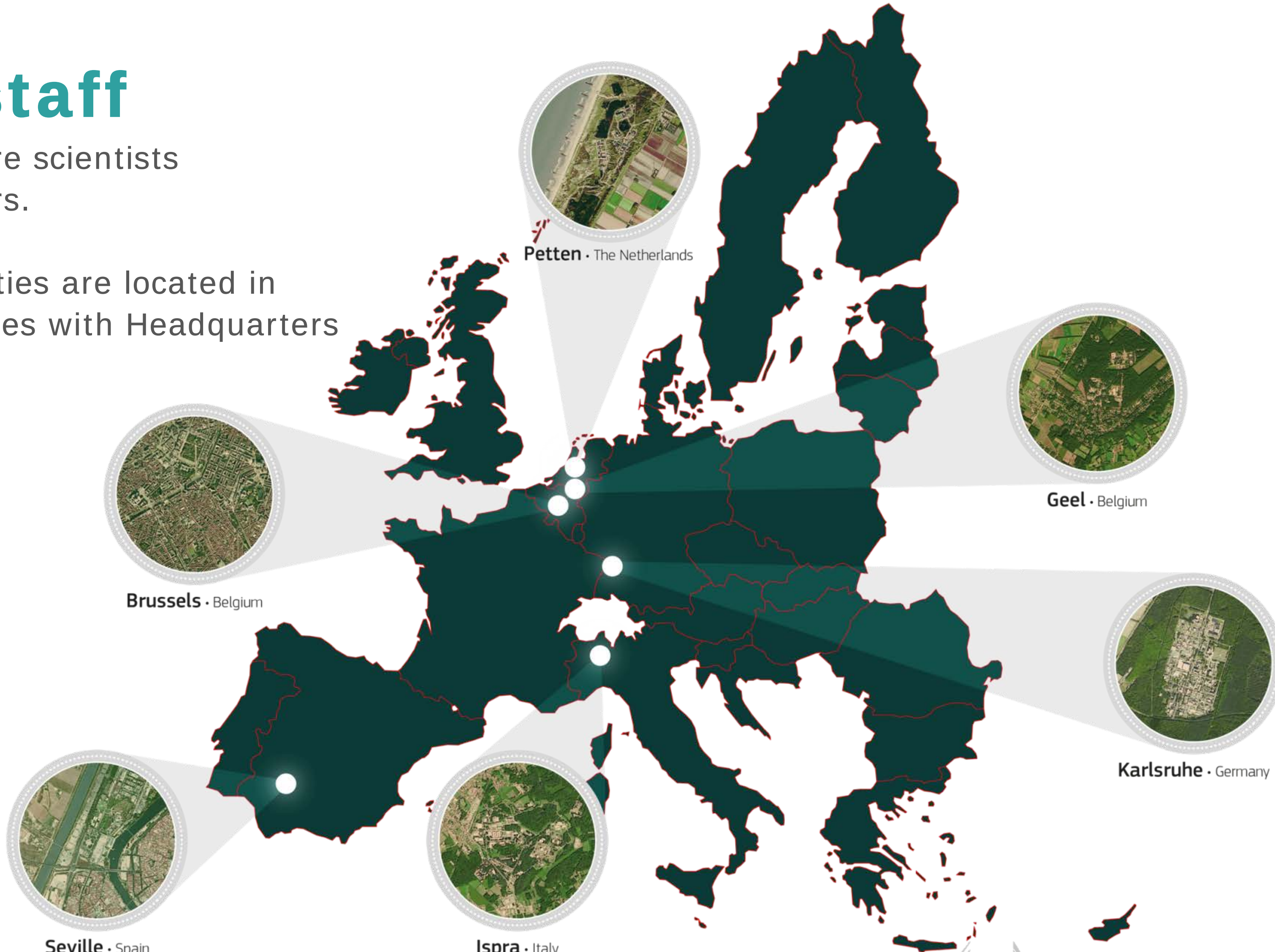
European Commission

# The Joint Research Centre at a glance

## 3000 staff

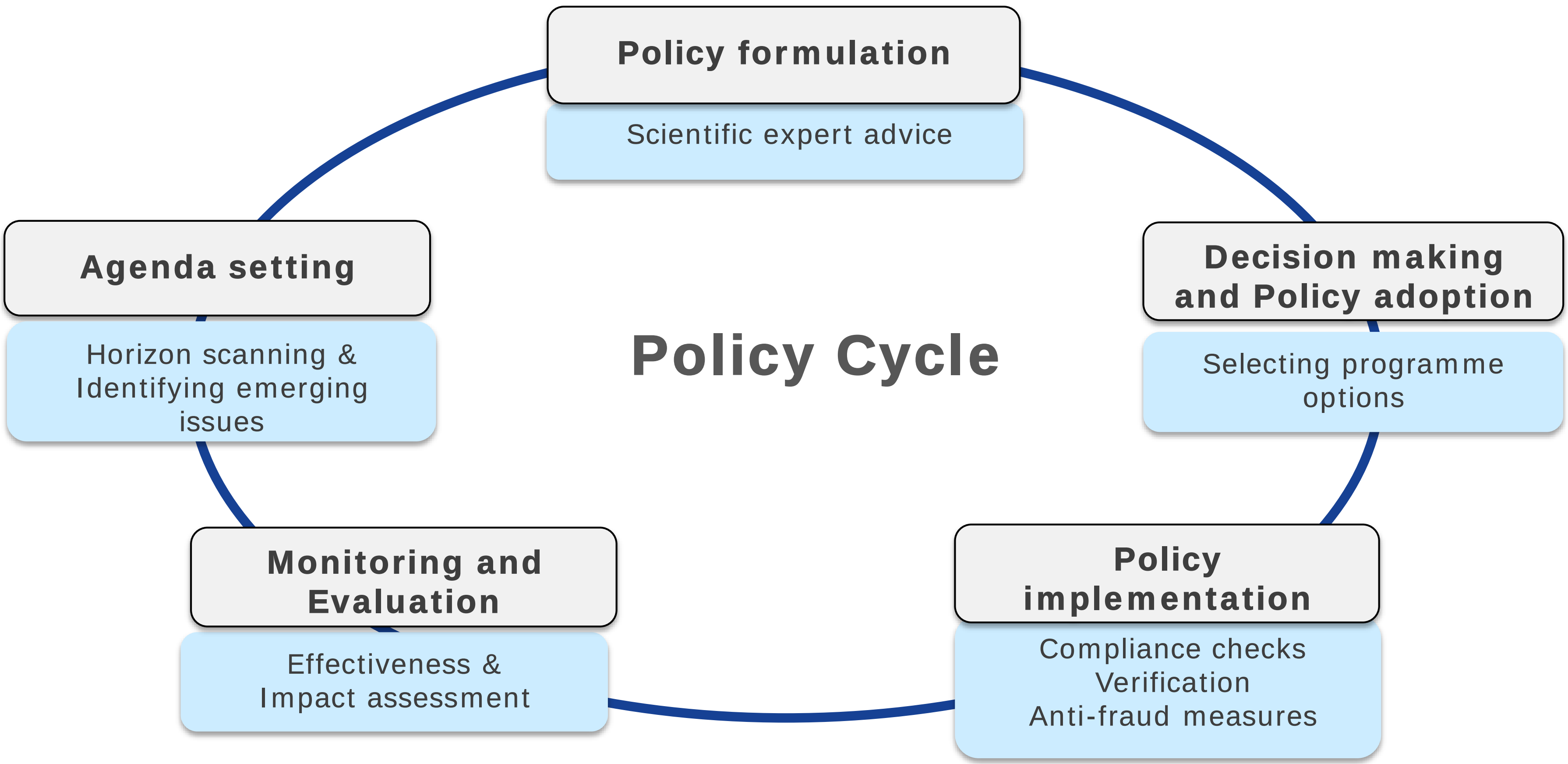
Almost 75% are scientists
and researchers.

Research facilities are located in
5 Member States with Headquarters
in Brussels




European
Commission

# The JRC in the EU Policy Cycle




Participants to the Policy Cycle: Civil Society, Cabinet, Commission, European Parliament, Council / Member States, Private Sector

# Chemicals Policy and Advanced Materials

The **Green Deal** (Dec. 2019) aims for a climate-neutral, zero-pollution, sustainable, circular and inclusive economy. **Innovative new materials** are mentioned as they can help to reach these goals. They need to be safe and sustainable.

The upcoming new **EU chemicals strategy for sustainability** aims to better protect humans and the environment against hazardous chemicals and encourage the innovative development of safe and sustainable alternatives.

# EU Regulatory Frame for Safety Assessment of Chemicals incl. Nanomaterials and Advanced Materials

REACH
CLP
TMR
Food
Cosmetics
Pesticides
Biocides
…

**ASSESS SAFETY of Chemicals before placing them on the EU Market**

**REGULATORY INFORMATION REQUIREMENTS**

**DATA and DATA COLLECTION**
**Physico-chemical and (eco)toxicological properties of chemicals; info. stored in databases**

**METHODS**
- repeatable, relevant and reliable
- recognised by regulators
- reflect scientific progress
- address animal welfare aspects
- cost-effective

**Test Methods Regulation (TMR) Regulation No 440/2008**
and subsequent adaptations to technical progress
**Good Laboratory Practice (GLP) Directive 2004/10/EC**

Ensure
- protection of human health & environment
- internal EU market

Partners: DG ENV, DG GROW, DG SANTE, DG RTD.

AA with DG ENV on test methods

# EU Chemicals legislation & Advanced Materials

- **Advanced Materials** (AM) are **covered by EU legislation** on chemicals, but are **not** explicitly mentioned nor **defined** in the chemicals legislation.
- The legislation is supported by e.g**. tools** for assessing risk / safety. These tools are mostly adapted to assessing issues for one substance at a time, and **rarely deal with mixtures and synergistic/antagonistic issues or the dynamic nature of some materials.**
- **Advanced Materials** are **complicated to define** unambiguously, as they are **transient in nature** (today's AM could be tomorrow's standard material), and seem to have **no characteristic that is common to all of them**; this is a challenge for developing specific legislation.

European Commission

# Next Step: Workshop on Safe and Sustainable Smart Nanomaterials

- **Understand safety information needs in a new area: Smart Nanomaterials,** also known as stimuli-responsive, multifunctional or active nanomaterials. They are a specific type of so-called advanced materials.
- These nanomaterials respond to specific external stimulants, such as temperature, pH, light or enzymes, by changing their properties and functions, which is utilised in e.g. sensors and targeted delivery systems, already in use in medical products (e.g. drug delivery) and electronics. Applications in agriculture, food, packaging and cosmetics are at research and development stage, and some have already been commercialised.
- The complex and dynamic nature of smart nanomaterials may raise concern regarding their safety and sustainability and the ability of the current regulatory framework to ensure it.

European Commission

# Next Step: Workshop on Safe and Sustainable Smart Nanomaterials

**WHO:** The workshop gathers developers, scientists and regulators to discuss the design, development, safety, sustainability, and legislative aspects of smart nanomaterials as well as related research needs.

**WHAT:** The aim is to outline current considerations of safety and sustainability aspects in the development of smart nanomaterials, current tools and their use and adequacy, and the needs and challenges in adequately addressing the safety and sustainability of smart nanomaterials by both industry and legislation.

Safe and Sustainable **Smart** Nanomaterials

European Commission

European Commission DGs JRC & RTD. Virtual Workshop on

## Safe and Sustainable Smart Nanomaterials

## Workshop agenda

**Wednesday 9 September**

Introduction

Session 1 – **Designing Smart Nanomaterials**

Session 2 – **From Safe-by-Design to Safe-and-Sustainable-by-Design**

**Thursday 10 September**

Session 3 – **Regulatory preparedness**

Session 4 – **Outlook: How to shift towards a more sustainable path?**

Wrap-up and conclusions

Joint Research Centre

# Next Step: Workshop on Smart Nanomaterials

- The safety of new materials can be promoted from their conception with the help of **Safe-by-Design**, an established systematic approach to assessing and ensuring the safety of a material or product as an integral part of the design process.
- In a similarly systematic approach, the evolving concept of **Sustainability-by-Design** aims to address the sustainability aspects of materials and products in development.
- **Safety and Sustainability by Design** combines both aspects.
- **Regulatory Preparedness** helps regulators to keep up with innovation in the development of new technologies, materials and products and to prepare appropriate legislation and other regulatory tools in good time for their arrival to the market.
- This is promoted by **FAIR data** (Findable, Accessible, Interoperable & Reusuable) through templates and database structures.

European Commission

# Next Steps

- The European Commission’s chemicals priorities with a perspective on advanced materials and nanomaterials: protection from risks to human health and the environment.
- Based on the understanding gained at the workshop the intention is to evaluate the applicability of the tools, e.g. for testing, and develop tools and methods for a safe innovation approach (SIA) building on Safe-by-Design and Regulatory Preparedness, promoting FAIR (Findable, Accessible, Interoperable & Reusuable) data through templates and database structures, leading in Governance for nanomaterials and advanced materials.

## Thank you to my colleagues:

Stefania Gottardo,

Paula Jantunen,

Agnieszka Mech,

Hubert Rauscher,

Juan Riego Sintes

For our Environment

Umwelt Bundesamt

ANSI-NSP Workshop Advanced Materials 19/20 August 2020

# Advanced Materials - Perspective of the German Environment Agency

Doris Völker

# Advanced Materials in the perspective of UBA

Umwelt Bundesamt

- heterogenous group of new or modified materials
- including (next generation) nanomaterials and nanostructured materials
- including materials beyond > 100 nm* with potential risks not solely determined by chemical composition, but may be additionally strengthened-by physical and morphological properties

⇨ ***No common understanding what Advanced Material include!***
***Complexity which goes beyond 1st generation nanomaterials!***

***Questions from a Competent Authority point of view:***

- Can current tools for risk assessment be applied properly?
- Which regulatory challenges do advanced materials entail, e.g. are they covered by the definition of a substance?
- Is safe use warranted?

*Materials exhibiting special functionalities (catalytic, optical, magnetic…), organic-inorgnaic hybrid materials, advanced polymers, materials with biological and chemical components, carbon materials…

# German Research Project on Advanced Materials

Umwelt Bundesamt

## Advanced Materials – Thematic conferences

## Assessment of needs to act on chemical safety*

**Run Time:** Summer 2019 – Summer 2021

**Objectives:**

- identify advanced materials and their (future) applications for human and environment which pose challenges for regulation
    - identify challenges for appropriate risk assessment and safe use
    - deduce recommendations for actions to assure safety of human and environment

**Elements:**

- **Survey** on advanced materials on classes, uses, existing definitions
- Approaches how to **categorize and prioritize** advanced materials
- Discussions in three **international thematic conferences** (Dec 2019, June/September 2020 and May 2021)

Ökopol Institut für Ökologie und Politik GmbH

BOKU ISR Institute of Safety and Risk Sciences
University of Natural Resources and Life Sciences, Vienna

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

*funded by the German Federal Ministry for the Environment & coordinated by the German Environment Agency

# Advanced materials - online conferences

# Identification of action needs on chemical safety

## Approaches for structuring the field, prioritisation and assessment

First online conference
**16 June 10:00 – 12:00 and 13:00 – 15:00 CET**

Umwelt Bundesamt

OECD BETTER POLICIES FOR BETTER LIVES

## Proposed structuring approach:

- 8 main cluster with several subclusters
  - Advanced Alloys
  - Advanced Polymers
  - Biopolymers
  - Porous Materials
  - Particle Systems
  - Advanced Fibres
  - Composites
  - Metamaterials

Giese, B., 1st Online Conference Advanced Materials, 16 June 2020

- Fact sheets on subclusters

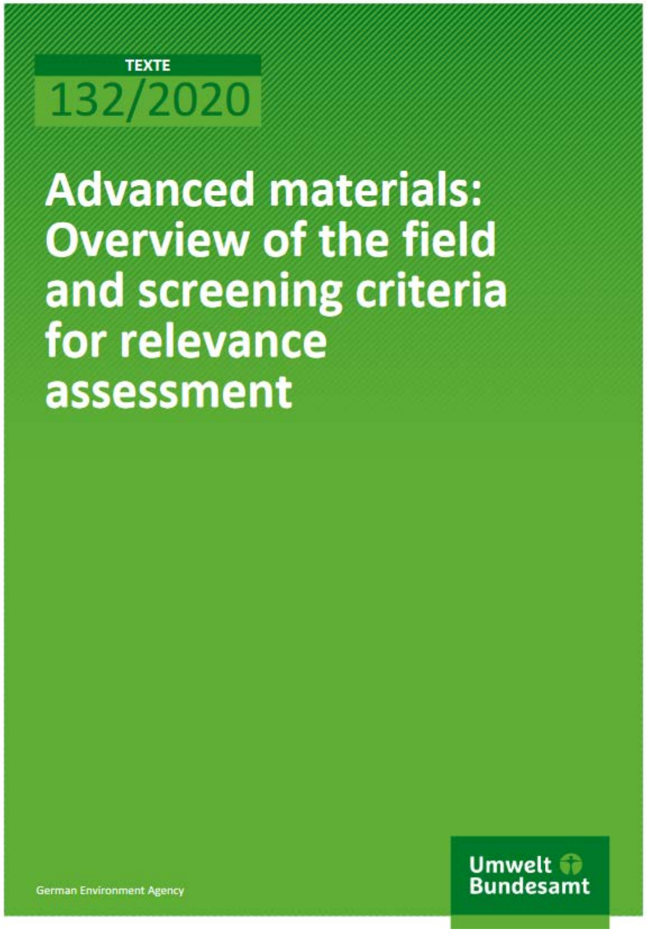
## Proposed criteria to prioritise for further action:

- Criteria deduced from 4 dimensions of relevance: *science, economy/technology, risk, regulation*
- *Aim:* Screen clusters/subclusters for priorisation of advanced materials "of concern" for further action:
  - Close data gaps
  - Check legal coverage
  - Assess possibilities for adequate risk assessment
  - Involve stakeholders…

Ökopol Institut für Ökologie und Politik GmbH

BOKU University of Natural Resources and Life Sciences, Vienna ISR Institute of Safety and Risk Sciences

# Publications of current project outcomes



TEXTE

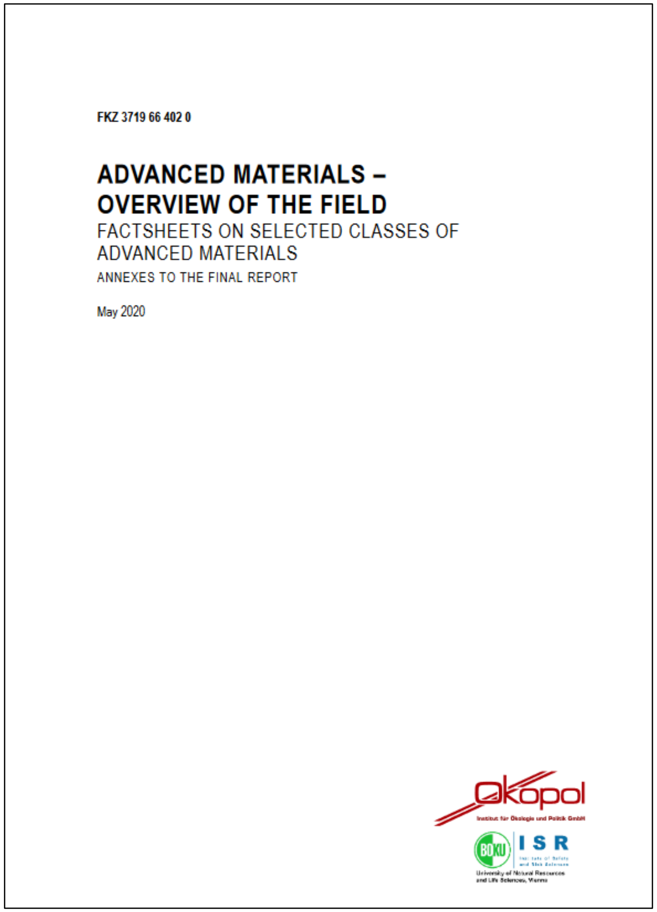
132/2020

Advanced materials: Overview of the field and screening criteria for relevance assessment

German Environment Agency

Umwelt Bundesamt

https://www.umweltbundesamt.de/publikationen/advanced-materials-overview-of-the-field-screening



FKZ 3719 66 402 0

ADVANCED MATERIALS – OVERVIEW OF THE FIELD

FACTSHEETS ON SELECTED CLASSES OF ADVANCED MATERIALS

ANNEXES TO THE FINAL REPORT

May 2020

https://oekopol.de/archiv/material/756_AdMa_Factsheets_final.pdf

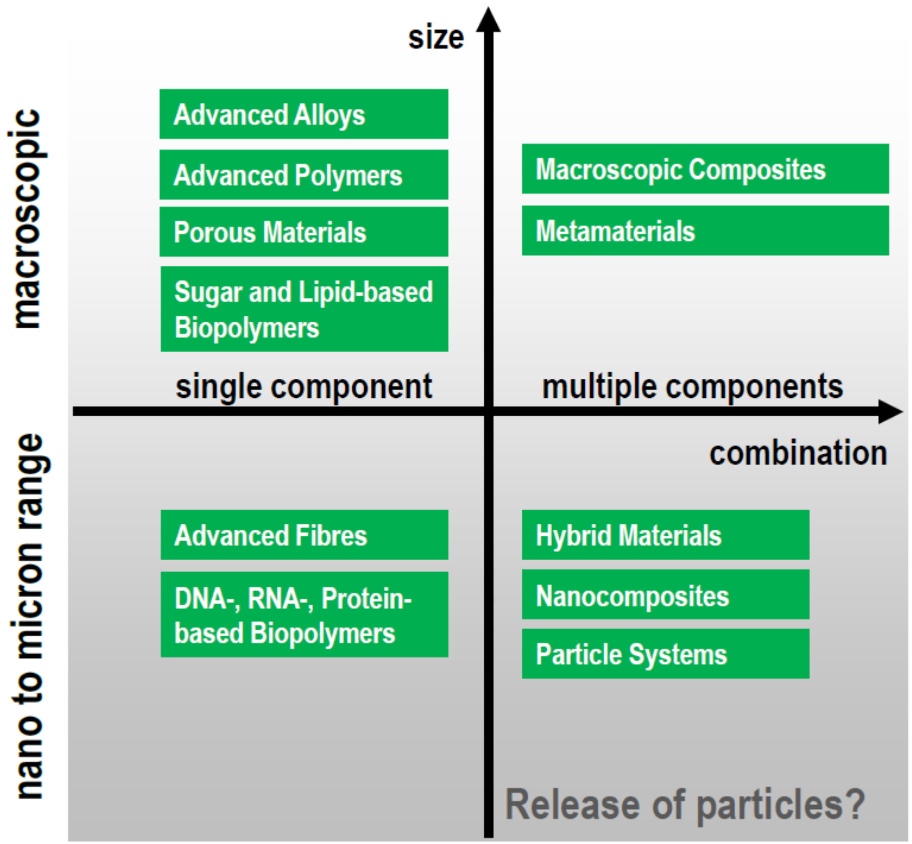
# Conclusions

Umwelt Bundesamt

## Goals of the ANSI-NSP Workshop

1. *Identify relationships and synergies between nanotechnology standardization activities and needs relative to advanced materials*

- Involvement of expert community for nanomaterials (plus experts specific for a certain cluster or area of interest, e.g. CE)
- Build on knowledge gained and approaches developed for nanomaterials (if possible, e.g. challenges related to particulate materials)
- **However**: Even though challenges might be similar, advanced materials may feature additional ones, more urgent as, or less relevant for nanomaterials!




Giese, B., 1st Online Conference Advanced Materials, 16 June 2020

## Conclusions

Umwelt Bundesamt

**Goals of the ANSI-NSP Workshop**

2. *How can we do better at identifying the gaps and the needs relative to Advanced Materials Standards, and how do we prioritize topic areas?*

- Don`t try define, but to delimit!

*Delimitation to „non-advanced": **materials that are rationally designed in order to fulfil the functional requirements of a certain application***

- Screen for relevant cluster of advanced materials for further action on, e.g.
  - Indications of hazard, exposure and risk
  - Lack of data on potential hazard or risk
  - Legal coverage
  - Appropriateness of tools for risk assessment
  - Contraints for circular economy and resource consumption
  - …

Umwelt Bundesamt

# Thank you for your attention!

Kathrin Schwirn
Doris Völker
Umweltbundesamt

kathrin.schwirn@uba.de
doris.voelker@uba.de

Next Online Conferenc e/s

Advanced materials - online conferences

**Identification of action needs on chemical safety**

Chemical safety concerns of advanced materials – advanced materials of concern

Second online conference
**15 September 10:00 – 12:00 and 13:00 – 15:00 CET**

Umwelt Bundesamt
OECD
BETTER POLICIES FOR BETTER LIVES

https://www.umweltbundesamt.de/en/topics/chemicals/nanotechnology

# ANSI-NSP Meeting on Advanced Materials

## Should Nanotechnology SDOs Expand Their Scope to Include Advanced Materials?

A Perspective from ASTM E56 (Nanotechnology)

Debbie Kaiser, NIST
E56 Chair

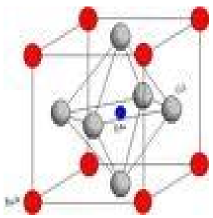
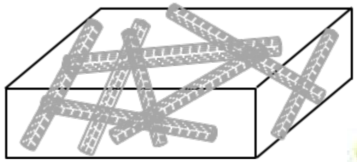
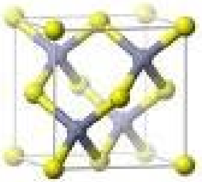
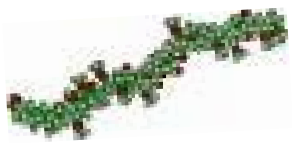
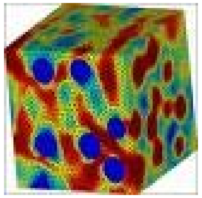
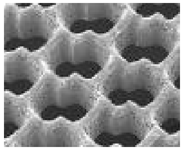
NIST
National Institute of Standards and Technology
U.S. Department of Commerce

ASTM INTERNATIONAL
Standards Worldwide

# Advanced Materials

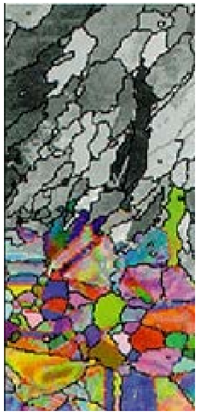
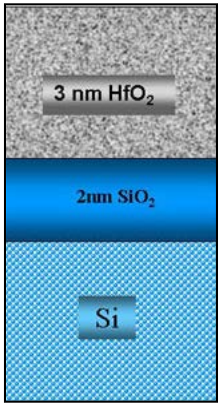
***Condensed phases, including***

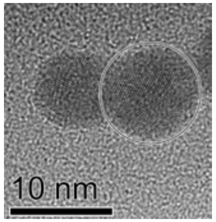
| | |
|---|---|
| Ceramics | Semiconductors |
| Metals | Biomaterials |
| Polymers | Hybrids |
| Composites | Fluids |

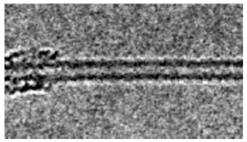
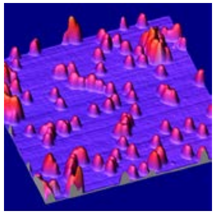







***…in all forms, including***

Bulk, porous
Multilayer
Tube, rod
Particulate

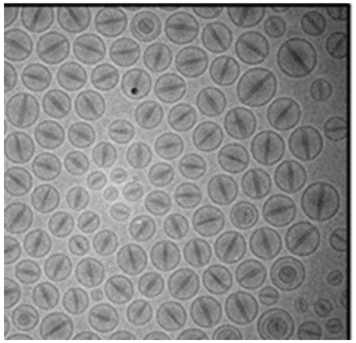



***…at all length scales***

nanoscale ⟶ microscale ⟶ mesoscale ⟶ macroscale

# Considerations

- Nanomaterials are a subset of advanced materials
- Most E56 standards and work items are not extensible to other types of advanced materials
  - Material-specific, *e.g.*, *liposomes*
  - Size-limited measurement method, *e.g.*, *Nanoparticle Tracking Analysis*
  - Specific sample preparation: *AFM*
- Initiate new standards applicable to advanced materials
  - What advanced materials?
  - For what purpose? *Regulatory, manufacturing*
  - Experience with nanomaterials indicates that *test methods* are often materials-specific
  - Challenging to recruit individuals to work on standards



Liposomes:
ASTM E3143-18b


https://imgs.xkcd.com/comics/standards.png

# ISO TC229 and Advanced/Emerging Materials

**Vladimir Murashov, PhD**

**Convenor, ISO/TC229 Working Group 3**

**Chair, U.S. TAG to ISO/TC229**

ANSI-NSP Workshop on Advanced Materials

August 20, 2020

# ISO TC229 Scope

*Standardization in the field of nanotechnologies that includes either or both of the following:*

- *Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications,*
- *Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.*

# ISO TC229 Scope

*Standardization in the field of nanotechnologies that includes either or both of the following:*

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- *Utilizing the **properties** of nanoscale materials that **differ from** the properties of **individual atoms, molecules, and bulk matter**, to create improved materials, devices, and systems that exploit these new properties.*

***Advanced/emerging materials?***

# ISO TC229 Scope

Size-dependent phenomena that enable novel applications are not strictly limited to the nanoscale (1-100 nm) as reflected in the scope. Examples:

- Agglomerates and aggregates with important three-dimensional structures formed from nanoparticles can be larger than 100 nm;
- Materials with unique/novel size dependent properties may consist of particle beyond 100 nm or with only a fraction of particles below 100 nm. In these cases, standards for nanomaterial and larger sized materials expressing the same properties/phenomena would ideally be consistent for commerce;
- In the medical field, materials engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to their dimensions, even if these dimensions fall outside the nanoscale range (e.g. up to 1000 nm) have been considered as applications of nanotechnology.

# ISO TC229 Activities related to advanced/emerging materials

- JWG1 Terminology
  - Study Group on definitions for advanced/emerging materials
- JWG2 Metrology
  - Measurement standards for graphene
  - Study Group on liposomes
- WG3 Health, Safety and Environment
  - Roadmap includes “nanomaterials and other advanced/emerging materials”

# ISO TC229 Activities related to advanced/emerging materials (cont.)

- WG4 Material Specifications
  - Standardization of the characteristics and test methods used in specifications for business to business transactions
  - Superparamagnetic beads
  - Porous alumina/silica

- WG5 Product Performance
  - Performance-based standards for nano-enabled or nano-enhanced products and applications
  - Biomedical applications: nanosensors

# Opportunities

- Focus on materials with unique, novel and emergent properties rather than an arbitrary size scale by expanding scope to include advanced/emerging materials
- Reinvigorate TC229 activities
- Continue utilizing and building on existing standards development framework, knowledge and expertise
  - Proactive paradigm for standards development
  - Horizontal structure for foundational standards to facilitate successful introduction of new materials into production and commercialization

# Challenges

- Need to define "advanced/emerging materials"

- Need to limit the scope
  - Exclude bulk materials, incidental nanoparticles, biomacromolecules, traditional materials, etc.

- Need to allay concerns of other TCs about scope infringement

- Need to attract additional experts

# Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

# Are we asking the right standards questions about advanced materials?

Opening comments to the ANSI Nanotechnology Standards Panel Advanced Materials workshop, August 20, 2020

*These are my speaker notes, and may not match precisely what I said!*
*Andrew Maynard, August 20, 2020*

I want to start with an anecdote. Back in the 1980's when I was in high school in the UK, a select number of students each year sat for the entrance exams for Oxford and Cambridge university. These were well-known for their gnarliness, and ability to trip unsuspecting applicants up.

I never sat the exams. But I do remember the rumors about them, and one in particular about one of the more challenging questions that sometimes came up, where candidates were asked to write an essay on the question "how long is a piece of string?"

Of course, the question – and to be honest l don't know how true these rumors were – if it existed, was designed to test intellectual and creative aptitude. There are, of course lots of ways it can be answered. But there is no actual quantitative answer to the question.

I mention this because the question is a useful metaphor for thinking about standards and how they apply to advanced materials, as well as their precursor in this particular conversation, nanomaterials.

What the question does rather well is to illuminate the difference between terms of art, and terms of science, when it comes to standards. Both are important, but each has a very different meaning and use. And conflating the two can lead to a whole lot of hurt.

Terms of science are evidence based. They're derivable They are traceable. And they are insulated from opinion – at least to a certain extent.

In contrast, terms of art encapsulate norms, expectations, opinions and perceptions that are not necessarily grounded in evidence, but that nevertheless grease the wheels that the world runs on.

Both terms of art and terms of science are vital to developing, establishing and applying standards. But using a term of art as if it's a term of science leads to a process of rationalization that's akin to asking how long is a piece of string and trying to convince people that you have a definitive answer!

So with that preamble, let me ask another question: As we consider standards for advanced materials – especially building off the standards work done on nanomaterials – are we looking at standards that are based on terms of art, or terms of science? And importantly, are we able to tell the difference?

This is a vital framing question to our discussions here. But there is an even more fundamental question that we need to address in this conversation: Why are we considering developing standards related to advanced materials in the first place?

Of course, there are many reasons why we develop standards, and why they are important. These include, but are certainly not limited to, quality control; scalable innovation; economic growth; competition; establishing a level playing field; and, of course, managing risks to health and the environment.

In approaching standards development in a specific domain, we need to have at least a sense of what the purpose of future standards is, what the most appropriate approach is that we should be taking, together with how we'll know if the standards are successful, and what the potential consequences of *not* developing standards are.

These are all important questions as we think about advanced materials. There is an additional question here though, and that is: how can what's been achieved with nanotechnology and engineered nanomaterials be usefully extended to advanced materials? And of course, this is the focus of this workshop.

At this point, it's worth asking something that may seem obvious, but is nevertheless helpful I think. And that is: What evidence is there that nanotechnology-related standards have led to measurable positive outcomes?

I have to assume here that there is clear evidence – there certainly should be if we are looking to extend successes in this domain to a broader range of materials. I can't answer this in a general sense because it lies outside my current work – I'd hope though that participants in this workshop can.

However, what I can provide is some insight into the nanotechnology standards landscape around environmental and health impacts.

Here, despite substantial work over the past decade or so, I fear there is been a muddying of the waters between terms of art, and terms of science. There's been a tendency to treat terms like "nanotechnology," "nanomaterial" and "nanoparticle" as if there is a scientific basis for them, whereas these are all ultimately terms of art.

Of course, we can define each of them in terms of size, and length scale, and this is what's been done. But from a functional perspective, the definitions are arbitrary. 100 nm, no matter how useful it is, is a number of convenience, not of science.[1]

Of course, I'm oversimplifying, and nano standards go way beyond a naïve assumption of a 100 nm cutoff. And I don't want to downplay the importance of work that has been done here over the past several years But if we don't recognize the nature of the foundations on which we are

[1] Maynard, A. D. (2011). "Regulators: Don't define nanomaterials." Nature **475**: 31.

thinking about building standards around advanced materials, we run the risk of building a house of cards that will ultimately fail us.

And here I want to be clear that I think there probably are standards that will be needed if we are to fully realize the promise of advanced materials. But the nature and purpose of these standards needs to be well-defined from the get-go.

To illustrate this, consider nanotechnology-focused health and environmental standards for a minute.

A key driver of nanotechnology risk-based standards was research that was carried out in the 1990's that indicated certain classes of fine particles elicited pulmonary responses that far exceeded those that were expected. And hypotheses began to emerge that the risks they presented were more closely associated with physical parameters such as size, specific surface area, and surface chemistry, rather than the more traditional metrics of bulk chemistry and mass.

These studies didn't come out of no-where though. They were built on a long tradition of aerosol research going back to the 1950's that recognized that the inhalation risk associated with occupational airborne particles is related to their physical and chemical form, and the region of the lungs they are capable of penetrating to.[2]

As a result of decades of research, standards were developed that defined potentially harmful materials based on their ability to reach vulnerable parts of the body, and modes of action that were mediated by their physical and chemical form.

In other words, these were standards that directly addressed the implications of complex materials interacting with sensitive biological systems. They were standards that were both evidence-based, and outcomes based. Interestingly, there was even discussion over half a century ago around using exposure metrics such as aerosol surface area and number.

In many ways, more recent health-based standards associated with engineered nanomaterials have been something of a deviation from this evidence-based approach. The term of art here came first – nanotechnology – followed by attempts to treat it as a term of science, with the result that the foundations of some nano-focused standards are probably less useful and more fragile than some of us would like.

With advanced materials, we have an opportunity to get back to basics, and to recognize and respect this term of art for what it is, while developing standards that are both fit for purpose and, where appropriate, evidence-based.

And just to underline this, advanced materials *is* very clearly a term of art. It has no fundamental scientific basis. It is dependent on context. And it is temporal.

[2] e.g. see Maynard, A. D. and E. D. Kuempel (2005). "Airborne nanostructured particles and occupational health." Journal Of Nanoparticle Research **7**(6): 587-614.

Because of this, we should be asking what the purpose is of standards that relate to what we broadly and indistinctly think of as advanced materials. We should also be asking what the needs and opportunities are here, and how we begin to address what we might consider as relevant functional behavior with actionable standards.

From a health and environment perspective, such relevant functional behavior will depend on exposure or dispersion – that is, the ability of materials to get to places where they can do harm – together with the ways in which these materials interact with biological systems that lead to harm once there.

This, to me, is an essential starting point – and it's one that focuses on what a material has the potential to do, not what it is called. And here, the stark reality is that nature doesn't care what we call a material, it just cares about how it behaves.

From this starting point, biological impact becomes the primary driver of standards. This is important, as existing materials that are used in new ways can lead to unexpected risks just as readily as new materials. And likewise, there is no reason to assume that new materials, by default, present new risks.

This challenge of focusing on behavior, rather than being guided by definitions based on terms of art, is one that a couple of colleagues and I set out to explore in our 2010 paper looking at what we termed at the time "sophisticated materials."[3] Here, I must confess that we chose this term "sophisticated materials" – which is yet another term of art – to try and break away from the conceptual baggage that comes with the terms "nanomaterials" and "advanced materials," although looking back, this probably didn't do us any favors citation-wise!

As we worked through what leads to materials raising risk red flags – in other words materials that are likely to slip under the conventional risk radar – we came up with five categories of materials that seemed to warrant particular attention. These included:

- Materials that demonstrate abrupt scale-specific changes in biological and environmental behavior, such that by changing the physical structure of the material it is possible to radically alter its risk profile.
- Materials that are capable of penetrating to organs and systems that are normally protected against exposure. For instance, materials where their size and structure is such that they are able to cross normally-impermeable biological boundaries.
- Active materials, that demonstrate marked changes in biological behavior based on their biological or environmental context.
- Self-assembling materials, that have the capacity to alter both form and risk profile *in situ*.

[3] Maynard, A. D., D. Warheit and M. A. Philbert (2011). "The New Toxicology of Sophisticated Materials: Nanotoxicology and Beyond." Tox. Sci. **120**(Suppl 1): S109-S129.

- And materials that otherwise exhibit biological mechanisms of interaction that lead to hazards which are not adequately captured by conventional hazard assessments.

These five categories could all describe “advanced materials.” But they could also equally well describe conventional materials used in new ways, or even existing materials that we haven’t taken seriously in the past, but probably should.

Of course, from a standards perspective, these criteria are not easy to work with. But they, or similar criteria, *are* amenable to being operationalized within standards that are both evidence based and outcomes based.

And importantly, because they don’t depend so much on terms of art, they help avoid materials slipping the net that don’t confirm to definitions of “advanced materials” and yet still have the potential to cause harm in ways that are not captured through conventional risk assessments.

Of course, environmental and health-based standards are just a small subset of potential advanced material standards. Yet this subset does illustrate the need to be very clear on why standards are being developed, and the potential dangers of building advanced materials standards on nanotechnology standards without fully understanding the limitations of these foundations.

So to wrap up, I want to come back to where I started with that question of how long is a piece of string. And here I wanted to acknowledge that string, of course, is an important product. It needs standards! Standards that define the properties, quality, uses, and a whole host of other aspects of different types of string.

But despite this, “how long is a piece of string” is the wrong question when it comes to developing standards, or at least useful ones.

And this is where I want to leave you – with the question: how do we know we’re asking the right questions with advanced materials?

Thank you.