A Regulator's Approach to Nanomaterials

S. Takatori, J. Wong

Department of Toxic Substances Control (DTSC)
California Environmental Protection Agency (Cal/EPA)
1001 I Street, Sacramento, CA 95814-2828 USA
Stakator@dtsc.ca.gov

ABSTRACT

The quest for a singular overarching regulatory definition of "engineered nanomaterials" is a lost cause; regulators need from experts in the field an improved chemical registry system to rapidly identify and scrutinize all emerging chemicals. Basing a regulatory strategy upon a singular overarching definition appears to be difficult, if not impossible, from both a scientific and consensus perspective. Instead, regulators should work with an updated chemical registry that includes a dynamic list of all emerging chemicals (including nanomaterials) with scientific evidence guiding the presence of environmental and/or health risks not captured by existing regulations. Unlike ongoing efforts to singularly define nanomaterials, an updated chemical registry would appear to be a more flexible and appropriate mechanism for triggering regulatory action in this evolving area of science.

Keywords: environmental health and safety, regulation, nanomaterial definition, oversight

1 INTRODUCTION

Policymakers and regulators appear to have a mistaken belief that a singular overarching definition of engineered nanomaterials is a requirement for any possible regulatory strategy. Like many in the past(*1, 2*), the Department of Toxic Substances Control's (DTSC) attempts(*3*) to arrive at such a definition were constantly challenged either from the perspective of scientific validity or consistency with prior efforts by other authoritative bodies(*4-6*). Although largely focused upon size, our pursuit of a definition appeared consistent in approach to others and was an attempt to avoid an artificial size gap by which materials would potentially escape regulatory scrutiny. We now believe that the quest for an overarching definition is the wrong strategy.

Definitions often identify whether or not a class of material is regulated at all by establishing a mechanism for triggering regulatory action. For example, the scope of the Environmental Protection Agency's (EPA) hazardous waste regulatory program depends heavily on the definition and interpretation of a "solid waste." The consequences of falling within the definition are clear and substantial because it establishes the standard for what materials would be regulated. With the advent of engineered nanomaterials, a similar strategy to develop its appropriate definition has been attempted by various authoritative bodies like the EPA(*7*), Health Canada(*5*), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of Australia(*6*), and the European Commission (EC)(*4, 8*). The exigency for proper nanomaterial regulation is understandable, given the 500 % increase in the number of nanotechnology-based consumer products in the last five years.(*9*) Furthermore, government officials' use of existing chemical regulations (like the Toxic Substances Control Act of 1976 and Registration, Evaluation, Authorization and Restriction of Chemicals) for relatively simple nanomaterials like carbon nanotubes has exposed some weaknesses. Early on, safety considerations were set aside based upon analogies made to macroscale carbon black. This strategy now looks to be inappropriate, since macroscale carbon black and nanoscale carbon nanotubes appear to have different chemical, physical, and biological properties. Efforts to make existing regulations applicable to these and the vast array of more complex nanomaterials appear to be hampered by the struggle for a clear "one-size-fits-all" definition.

In his recent, poignant commentary, Maynard(*10*) expresses concerns over the absence of science in ongoing strategies for nanomaterial oversight, in particular over its regulatory definition. We agree with his views that a "one-size-fits-all" definition inevitably fails to provide scientific justification in favor of specific standards and criteria for triggering regulatory action. An equally important and vexing struggle in pursuit of a unifying definition has been to achieve consistency across all authoritative bodies. Just on the basis of size cutoffs alone, consensus has been difficult to reach. Many organizations like the EC(*4, 8*), International Organization for Standardization (ISO)(*11*), the Danish Ministry of the Environment(*12*), the NICNAS(*6*), and Health Canada(*5*) have used 100 nm as the single upper size threshold for a material to be evaluated as a "nanomaterial." Others advocate an upper threshold of 300 nm for nanotechnology-based pesticides(*13*), whereas DTSC(*3*) and the Food and Drug Administration (FDA)(*14*) have recommended sizes up to 1000 nm to include larger (than 100 nm) materials that retain and exhibit nanoscale properties. Yet another suggestion(*15*) is to focus on the unique properties and phenomena associated with

nanomaterials rather than a rigid definition based on size. To preclude a potentially harmful nanomaterial from slipping through the regulatory net, government regulators must reach a consensus not only on size, but on a near-infinite set of parameters: man-made versus naturally produced, particle size distribution, specific surface area, surface modification and charge, weight versus particle number concentration, and other physical-chemical characteristics, in addition to standards in measurement and analysis. It appears that the struggle for consensus has propelled authoritative bodies to arrive at definitions that are a reflection of approach and policy expediency rather than comprehensive scientific consideration. Is a material not a nanomaterial if its size exceeds the defined "limit" by 1 nm? Reliance upon a singular overarching definition appears to be the wrong strategy.

2 CHEMICAL REGISTRY

We propose an alternative approach. Policymakers and regulators need from experts in the field an improved chemical registry system with a dynamic collection of all emerging chemicals and their material property information. Unlike ongoing efforts to singularly define nanomaterials, an updated registry is based on existing infrastructures of chemical identification, like the Chemical Abstracts Service (CAS) Registry Numbers and the IUPAC International Chemical Identifier (InChI). For traditional chemicals, these registries have served as the harmonized reporting system for various nomenclatures and disciplines used by regulators and industries. For example, the CAS Registry Number "58-08-2" codes for caffeine. With this identifier, we have access to a wealth of information about caffeine's thermodynamic, crystalline, and other physical and chemical properties. By assigning a unique numerical identifier to every chemical substance, there is no ambiguity in the material or property of interest. The CAS Registry is updated daily, validated quickly and reliably, internationally recognized, and contains chemical-specific substance information.

With the advent of nanomaterials, however, existing registries appear inadequate. The CAS Registry has entries for carbon black (1333-86-4) and fullerene (C_{60}) (99685-96-8), each given a numerical identifier distinct from that of elemental carbon (7440-44-0). Yet nanomaterials like silver, titanium dioxide, or zinc oxide are given the same CAS Number as their macroscale counterparts. Existing registries seem incapable of keeping up with the vast array of sophisticated materials. Exotic materials like quantum dots (QDs), which can be engineered as a hierarchical assembly of various components—cadmium selenide core, zinc sulfide shell, and oligomeric phosphine coating, for instance—appear not to classify as "unique chemicals" under CAS.

We, thus, advocate for an improved registry robust enough to capture all emerging chemicals, irrespective of their complexity in physical form or functionality. The registry would be a dynamic collection of all emerging chemicals loaded with material property information like size, zeta potential, crystallinity, and other thermodynamic data. The registry can readily amalgamate Maynard's(*10*) suggested science-based "trigger points" to help inform the thresholds at which regulations should apply. Each entry would include scientific data on how the material may potentially harm public health and the environment in ways not captured by existing regulations. Maynard's strategy would then allow the registry to be a direct tool for implementing a triggering mechanism. We further agree with his view that regulators must confront all emerging chemicals rather than treating nanomaterials as a distinct class of material. The updated registry would work on all emerging chemicals (not just nanomaterials) and make no prior assumptions or generalizations about their risks. And unlike a black-and-white singular definition, the updated registry would be chemical-specific, grounded in existing infrastructure, and readily applicable in a regulatory framework.

We understand that such a system would require effort and time, especially with the predicted sophistication of future materials. Because the properties and potential risks of a material may depend critically on the particular context and environment they are in, the registry would require separate entries for each set of conditions. A skeptic may further argue that an updated registry is impractical because complex nanomaterials like QDs have near-infinite variability in core/shell assemblies. However, the CAS Registry has faced little difficulties processing near-infinite structural iterations of many traditional organic compounds. For example, 1,2, 1,3, and 1,4-dichlorobenzene differ only by the location of one chlorine atom, but are each given unique CAS numbers and entries.

The updated registry would be a direct tool for implementing a triggering mechanism. Under this strategy, an emerging chemical would automatically be a concern for action if it is on the registry and scientific evidence reveals potential environmental and/or health risks. A regulated material would no longer be one that meets a rigid definition but instead one that is simply listed on the registry with evidence calling for a possible need for regulatory action.

3 CONCLUSIONS

In the long term, it is our opinion that a harmonized reporting system is needed to identify and characterize engineered nanomaterials for regulatory purposes. An updated chemical registry would provide regulators with an unambiguous identification of all emerging chemicals, including nanomaterials. Basing a regulatory strategy upon a singular overarching definition appears to be the wrong approach from both a scientific and consensus perspective. In the near term, government regulators could avoid such problems by simply listing all nanomaterials of potential regulatory concern.

DISCLAIMER:
The ideas and opinions expressed herein are those of the authors and do not necessarily reflect the official position of the State of California.

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