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ARTICLE

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I. INTRODUCTION

The definitional problem of nanomaterials—namely, what exactly are nanomaterials with regard to regulation—has attracted relatively little attention from academics. Nonetheless, the definitional problem is certainly important: the scope of the definition or definitions may well dictate what uses of nanomaterials and risks from them come to be known by the public at all, and also may dictate how well regulatory agencies address risks once they are known. More than that, the issues raised by the project of formulating regulatory definitions of nanomaterials are ones that are at the core of regulatory debates that extend far beyond nanomaterials, however defined. If we "get it right" with nanomaterials, we thus may have a model for defining other emerging technologies.

At first blush, however, the question of how we define nanomaterials for purposes of health, safety, and environmental regulatory regimes may seem like a hyper-technical question of limited interest, at least to non-scientists. Consider, for example, a recent definition adopted by the Europe Commission:

> "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of

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> the particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm.[1]

This sentence that the European Commission put together is not exactly suggestive of anything interesting to a non-technical audience (or perhaps any audience). But in reality, how we will and should define nanomaterials for regulatory purposes is not simply a technical matter. It cannot be purely dictated by science, although it should be informed by it. Rather, the definitional debate regarding nanomaterials has a great deal to do with the relationship between government and industry, the pervasive problem of how to manage uncertainty as to risk, and the need for institutional structures that can be stable enough to garner political legitimacy but that are nimble enough to evolve along with changes in technology and in the understanding of risks from technology. In other words, the project of defining nanotechnology raises the same issues as regulation generally.

This Article reviews regulatory attempts to define nanomaterials to date, including the European Commission's definition. It then sets forth and explains why agencies should adopt what I am calling an information-forcing definition of nanomaterials. Nanomaterials implicate the same informational problem as many other substances or practices that are the subject of political and legal debate: that is, we (the public) know enough to know that there are some risks but not enough to specify and assess those risks. We know risks are posed by some kinds of small-scale materials in some contexts, but not enough is known to define the universe of which particular materials pose risk and which do not (or how much risk is posed by those materials that do pose risk). Regulators, therefore, do not know enough to specify the health and environmental risks from nanomaterials with any precision. Regulatory definitions are, therefore, needed that facilitate the production and sharing by industry of information about the small-scale materials they use, why they use them, and what behaviors those materials exhibit that may translate into human health and/or ecological risk. The

1. Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial, 2011 O.J. (L 275) 38-40 [hereinafter Definition of Nanomaterial], *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011H0696:EN:NOT .

regulatory definitions should be structured so as not only to force information from industry, but also to force, or at least encourage, agencies not to give in to powerful forces of bureaucratic inertia and stick with regulatory definitions even after emerging science and other public information suggest they are obsolete.

II. A DEFINITION THAT DOES NOT WORK: CHEMICAL IDENTITY

It may be helpful to begin by addressing three terms: nanotechnology, nanoparticles, and nanomaterials. Nanotechnology generally refers to the industry involved in manufacturing or using nanomaterials in some way; the term encompasses both techniques to create and manage nanomaterials and nanomaterials themselves.[2] Nanomaterials contain one or more nanoparticles.[3] A nanoparticle is a single particle at the "nano" scale, which in the conventional scientific discourse, means that a particle has at least one external dimension that is less than one hundred nanometers in length.[4] A substance or material may consist of particles of different sizes, some arguably "nano" and others not. One question is whether a material containing some nanoparticles (however defined) should be considered a nanomaterial, and when. How much of a material has to consist of nanoparticles in order for it to be a nanomaterial? And should it matter whether the nanoparticles are tightly bound to other particles, not that tightly bound, or essentially unbound?

However one answers these questions, the definition of nanomaterial builds on the definition of nanoparticle, so an essential task is to define "nanoparticle." Again, for conventional scientific discourse, there is an answer—a particle with one dimension measuring less than one hundred nanometers in length.[5] In other words, a particle with at least one very tiny

2. *What Is Nanotechnology?*, NANO.GOV, http://www.nano.gov/nanotech-101/what/definition (last visited Jan. 15, 2013).

3. EUR. AGENCY FOR SAFETY & HEALTH AT WORK, WORKPLACE EXPOSURE TO NANOPARTICLES 7 (June 3, 2009), *available at* http://osha.europa.eu/en/publications/literature_reviews/workplace_exposure_to_nanoparticles.

4. *Id.* at 13.

5. *Id.*

dimension. However, the conventional scientific definition does not tell us what should be the regulatory definition. To the extent we want particular regulatory attention to nanoparticles, or more broadly nanomaterials containing nanoparticles, we do not necessarily want to employ the conventional scientific definition unless that definition captures a category of materials that poses some particular risk.

Nonetheless, the scientific literature does not make, let alone support, that claim. Scientists use a conventional definition of nanoparticle simply as a descriptive convenience. The scientific studies of nanoparticles (as per the conventional definition) suggest that some of them may have adverse health and environmental effects depending on the composition, size, shape, configuration, coating, and contextual application or use, as well as other factors that distinguish one nanoparticle or material from another.[6] There is enough evidence to conclude that certain nanoparticles in certain contexts pose risks, but there is by no means evidence to suggest that most or all do.[7] Moreover, even with respect to those nanomaterials that have received the most attention, such as certain carbon nanotubes, we have an incomplete characterization of the risks.[8]

An initial response to the calls for regulatory attention to nanoparticles was to sidestep altogether the issue of definition and size and focus instead on the chemical identity of substances at the nanoscale.[9] In this view, a nanoparticle or nanomaterial does not require attention as a new subject of regulatory inquiry as long as the molecular identity of the substances at the nanoscale is no different from that of other substances that have already been reviewed and essentially approved for unrestricted

6. *Id.* at 5.

7. *See id.*

8. For discussions of what is known and not known about nanomaterials, see Kimberly A. Gray, *Five Myths About Nanotechnology in the Current Public Policy Debate*, *in* THE NANOTECHNOLOGY CHALLENGE: CREATING LEGAL INSTITUTIONS FOR UNCERTAIN RISKS (David A. Dana ed., 2011).

9. EUR. AGENCY FOR SAFETY & HEALTH AT WORK, *supra* note 3, at 49; *see also* U.S. EPA, TSCA INVENTORY STATUS OF NANOSCALE SUBSTANCES–GENERAL APPROACH (2008), *available at* http://epa.gov/oppt/nano/nmsp-inventorypaper 2008.pdf.

use by regulators.[10] For example, if a substance contains nanoparticles of silver, the substance would be considered unproblematic as long as non-nano ("bulk" or "coarse") versions of substances made of silver have been deemed acceptable without regulatory restriction.[11]

As an example of this approach, consider guidance offered by the United States Environmental Protection Agency (EPA) in 2008 regarding the status of "nanoscale substances" under the Toxic Substances Control Act:

> EPA has not used particle size to distinguish substances that are known to have the same molecular identity for the purposes of the TSCA Inventory. In determining whether a nanoscale substance is a new or existing chemical, the Agency intends to continue to apply its current Inventory approaches based on molecular identity, rather than focus on physical attributes such as particle size. . . . Although a nanoscale substance that has the same molecular identity as a non-nanoscale substance listed on the Inventory differs in particle size . . . EPA considers the two forms to be the same chemical substance because they have the same molecular identity.[12]

While this approach had an obvious appeal to regulators seeking not to become entangled in the potentially very complicated regulatory project of dealing with nanomaterials, it meant that nothing would be done about nanoparticles that posed risks precisely because they were nanoscale materials. The principal motivation behind the calls for regulatory frameworks for nanomaterials—and hence the need for a regulatory definition of nanomaterials—relates to the possibility that their small size may result in behavior that could pose a risk to human health or the environment. As the report of the European Union's Joint Research Center describes, there seem to be two distinct concerns related to size.[13] One concern is that very small materials may be

10. TSCA INVENTORY STATUS, *supra* note 9.

11. *See id.*

12. *Id.* at 5-6.

13. *See* EUROPEAN UNION: JOINT RESEARCH CTR., CONSIDERATIONS ON A DEFINITION OF NANOMATERIAL FOR REGULATORY PURPOSES (2010), *available at* http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf [hereinafter JRC REPORT].

harmful simply because of where they may travel.[14] The materials in very small form may be able to permeate barriers in the human body or other natural systems that were not designed to protect against such small materials, and these materials thus may enter into areas (such as the human brain) where they could cause harm.[15] This concern does not appear to be inherently limited to materials that are one hundred nanometers or less, and could, depending on the context or environment in which the material would be introduced, be implicated by larger materials.[16]

The second concern is that at very small sizes, the laws of physics apply to particles differently and hence very small particles can display novel properties that are not found in "bulk" or "coarse" versions of the same elements or chemical compositions.[17] While novel properties can be good and indeed explain why investments are made to create nanoparticles and nanomaterials, what may be a good or benign property in some contexts could be risky in others. In addition, materials that have some desirable, selected-for novel properties could have other undesirable, not-understood, not-selected-for novel properties. From the perspective of either concern, it is not relevant that the molecular identity of a substance at the nano-scale is identical to that of a bulk substance that has been determined by regulators as not posing risks warranting regulatory attention.[18]

14. *Id.* at 7.

15. *See*, *e.g.*, Ben Harder, *Conduit to the Brain: Particles Enter the Nervous System Via The Nose*, SCI. NEWS, Jan. 24, 2004, http://www.sciencenews.org/view/generic/id/4660/title/Conduit_to_the_Brain_Particles_enter_the_nervous_system_via_the_nose. According to Dr. Denison of Environmental Defense, the "surprising results" in these studies of nanoparticles include that "[t]hey can cross from the lung, when inhaled, directly into our blood." *Environmental and Safety Impacts of Nanotechnology: What Research is Needed?*: *Hearing Before the H. Comm. on Science*, 109th Cong. 1 (2005) (statement of Richard A. Denison, Ph.D., Senior Scientist, Environmental Defense).

16. JRC REPORT, *supra* note 13, at 26.

17. *See id.*

18. The novelty of behavior at the nanoscale also helps explain why one cannot dismiss nanomaterials as posing *de minimis* risks on the grounds that the mass of these materials is so modest as to make them an unproblematic addition to human or non-human ecological systems. At the nanoscale, surface area, charge, and reactivity may be much more important than mass. *See, e.g.*,

III. THE CURRENT DEFINITION DEBATE

Recent efforts at defining nanomaterials for regulatory purposes in the United States and Europe suggest several different choices that regulators face in addressing nanomaterials. These include:

- Whether to offer a firm definition of nanomaterials as a category at all or simply choose not to have a regulatory definition for the category;
- Whether to focus on all substances at the nanoscale or only those that are "engineered," that is, that are not "natural;"
- Whether to focus solely on an "objective," physical definition of nanomaterial or a "subjective," functional, novel-properties-oriented definition;
- Within the scope of the physical definition, whether to contain the scope to the conventional scientific definition of 1 to 100 nanometers, and whether to extend the definition to a material containing any nanoparticle or to limit the definition to material containing a threshold amount or proportion of nanoparticles; and
- Whether the definition of nanomaterials should vary by the extent and intensity of likely human exposure to the materials.

Each of these points of contention, or possible contention, is briefly reviewed.

M.E.J. PRONK ET AL., NANOMATERIALS UNDER REACH: NANOSILVER AS A CASE STUDY 17 (2009), *available at* http://www.rivm.nl/bibliotheek/rapporten/601780003.pdf. Mass-based definitions also are insensitive to context: even a very light substance that is so small as to lodge in sensitive parts of the human body (such as the brain) that usually block out intruding substances may warrant attention. For these reasons, mass- or volume-based regulatory regimes, such as the E.U.'s REACH, unless modified, arguably do not properly address nanomaterials. In the E.U.'s REACH, in the context of bulk industrial chemicals, there is an implicit exclusion from registration requirements for any chemicals for which less than a ton is produced or imported annually in the E.U. Despite its one ton per year threshold, the European Commission since at least December 2006 has expressed the view that REACH encompasses materials produced at the nano-scale that do not meet that threshold. *See* Lynn L. Bergeson, *REACH and Nano* (May 23, 2007), http://nanotech.lawbc.com/2007/05/articles/international/reach-and-nano/.

A. To Define or Not Define

In practice, many regulatory agencies in the United States and elsewhere have chosen not to address nanomaterials as a category and hence have avoided the definitional question, despite the fact that nanomaterials are an issue that is clearly part of the scientific and public policy discourse. One reason agencies may have chosen not to define nanomaterials is that their leadership does not believe a definition for the category would be useful, at least given the current limited scientific understanding of the behavior of nanoscale materials. Another reason may be that business entities are lobbying quietly, or not so quietly lobbying, in support of that view. One commentator closely linked to what might be termed the nanotechnology industry has suggested this explanation:

> Many government agencies have been reluctant to define terms pertinent to this emerging technology in the absence of additional data and information recognizing that the consequence of non-compliance with a regulatory mandate invites monetary and other unintended consequences. . . . The reason why many regulatory agencies have been reluctant to embrace definitions for regulatory purposes is that many believe a one-size-fits-all approach is scientifically indefensible and likely to do more harm than good. The debate will continue for some time. In the interim, stakeholders need to remain vigilant in monitoring global initiatives and try as best as possible to encourage regulatory agencies to define no term prematurely or inappropriately. The consequences of a rush to judgment will not help advance regulatory goals, may well confuse an already muddled area, and compromise the commercialization of a promising technology.[19]

The United States Food and Drug Administration (FDA) has come close to advocating a non-definition definition of nanomaterials, and hence has placed itself somewhere toward the do not define end of the define/do not define debate. Under FDA's approach, in considering whether a product contains

19. Lynn L. Bergeson, *To Define or Not to Define: The War of Words*, NANOTECHNOLOGY NOW, Sept. 2, 2011, http://www.nanotech-now.com/columns/?article=572.

nanomaterials, the agency will consider both objective physical criteria, specifically size, and novel properties associated with risks regardless of size.[20] However, there is no definitive commitment as to what FDA will treat as a nanomaterial or product containing nanomaterials. Thus, according to draft guidance:

> When considering whether an FDA-regulated product contains nanomaterials or otherwise involves the application of nanotechnology, FDA will ask: 1. Whether an engineered material or end product has at least one dimension in the nanoscale range (approximately 1 nm to 100 nm); or 2. Whether an engineered material or end product exhibits properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer.[21]

Consistent with the tentative "when considering" and "will ask" language, FDA also affirms that:

> FDA has not to date established regulatory definitions of "nanotechnology," "nanoscale" or related terms. . . . Based on FDA's current scientific and technical understanding of nanomaterials and their characteristics, FDA believes that evaluations of safety, effectiveness or public health impact of such products should consider the unique properties and behaviors that nanomaterials may exhibit.[22]

20. U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERV., CONSIDERING WHETHER AN FDA-REGULATED PRODUCT INVOLVES THE APPLICATION OF NANOTECHNOLOGY: GUIDANCE FOR INDUSTRY III(A) (2011), *available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm.

21. *Id.*; *see also* U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERV., DRAFT GUIDANCE FOR INDUSTRY: SAFETY OF NANOMATERIALS IN COSMETIC PRODUCTS II (2012), *available at* http://www.fda.gov/Cosmetics/Guidance ComplianceRegulatoryInformation/GuidanceDocuments/ucm300886.htm (adopting same language). For an approving discussion of the FDA approach, see Andrew Maynard, *A Nanotechnology Regulation Hat Trick From the US Federal Government*, 2020 SCIENCE, June 10, 2011, http://2020science.org/2011 /06/10/a-nanotechnology-regulation-hat-trick-from-the-us-federal-government/.

22. U.S. FOOD & DRUG ADMIN., *supra* note 20, at III.

The upshot of the FDA approach may be "we know it when we see it." This approach assumes that regulated entities should and will fully consult with the agency to discuss whether a product may contain nanomaterials and whether that requires additional regulatory review; according to FDA's Commissioner, "industry and developers should keep both of these broad size- and property-related factors in mind when considering whether their products might fall within FDA's attention for nanomaterials and are encouraged to consult with the agency early in their development process to resolve any uncertainties."[23] The responsibility for bringing materials to FDA's attention thus rests with business entities that make products subject to FDA approval. (As I suggest below, that assumption of industry eagerness to consult of its own accord, on its own initiative, may be unrealistic.)

What is the case for not defining nanomaterials as a regulatory category? The best answer to that question has been provided by Andrew Maynard, a leading scholar on the risks posed by and regulation of nanotechnology, and a person who cannot at all be characterized as simply advocating for industry interests. His argument appears to be that general regulatory definitions for nanomaterials may result in both over-regulation and under-regulation, and hence a specific regulatory definition of nanomaterials is undesirable.[24] He believes that many nanomaterials, defined by any plausible size criteria, do not all—or even almost all—pose risks based on the available and evolving scientific evidence.[25] Thus, any nanomaterials definition will be too broad and taint many materials that pose no risk. Conversely, any definition of nanomaterials will leave out some specific materials where dimension-related effects pose risks. Maynard suggests we should not seek to define and regulate nanomaterials as such, but take each material and product containing nanoscale materials as a unique case within a unique context and evaluate that case based on a range of factors that the available science suggests may be relevant:

23. Margaret A. Hamburg, *FDA's Approach to Regulation of Products of Nanotechnology*, 336 SCIENCE 299 (2012).

24. Maynard, *supra* note 21.

25. *Id.* at 2.

> With policy-makers looking for clear definitions on which to build "nano-regulations," there is a growing danger of science being pushed aside. . . . But it is becoming clear that many parameters other than size modulate risk, including particle shape, porosity, surface area and chemistry. Some of these parameters become more relevant at smaller scales—but not always. The transition from "conventional" to "unconventional" behaviour, when it does occur, depends critically on the particular material and the context. A "one size fits all" definition of nanomaterials will fail to capture what is important for addressing risk.[26]

B. Engineered or Not

Almost all proposed regulatory definitions of nanoparticles or nanomaterials limit the scope of the category to substances that are engineered, meaning manufactured, by human effort. That nanomaterials for regulatory purposes be engineered at the nanoscale is important for several reasons. First, because an entity is unlikely to engineer something at the nanoscale unless the material is expected to have novel properties, engineered materials are likely to display novel properties.[27] It is precisely such materials that implicate the concerns about unusual particle behavior that motivate the calls for the development of a regulatory framework for nanomaterials. Materials that are produced at a nanoscale inadvertently or by accident, or simply as a byproduct of the achievement of a goal unrelated to the nanoscale materials, are less likely to be characterized by novel properties.

That said, there are difficulties in tying a regulatory definition to a concept of "engineered" because it can be hard to know what is precisely meant by the concept, at least in the absence of a clear definition. Does engineered production include production where the manufacturer reasonably should have known it was creating a nanoscale material but for whatever reason did not know? Does intentional production, for example,

26. Andrew Maynard, *Don't Define Nanomaterials*, 475 NATURE 31 (2011) (Maynard had previously advocated for the regulatory definition of nanomaterials).

27. DAVID A. DANA, THE NANOTECHNOLOGY CHALLENGE: CREATING LEGAL INSTITUTIONS FOR UNCERTAIN RISKS 112 (2012).

include the production of a nanoscale material that is an incidental byproduct of the production of another non-nanoscale material if the manufacturer is in fact aware of the byproduct and its nanoscale dimensions?[28]

These difficulties in defining what engineered means could explain why, in contrast to other regulatory authorities, the European Commission has excluded "engineered" or even "intentionally produced" from its proposed definition of nanomaterials.[29] According to the European Commission's recommendation, its definition of nanomaterials "covers natural, incidental or manufactured materials."[30]

C. "Objective" Physical or Subjective "Functional" Criteria or Both?

Assuming that an agency accepts the need to define nanomaterials as a distinct category, and even assuming it limits that category to engineered materials, there remains the question of what criteria will be used to distinguish nanomaterials from all other materials. One difference in proposed definitions has to do with whether the definition should track physical criteria that in theory might be specifically measurable and hence, in a limited sense, objective. Size is the most obvious such criteria, and so far the only one included in any of the proposed definitions.[31] The

28. There is a strong case for carving out an exception to the regulatory definition for nanomaterials for those materials that were in production and use long before the last twenty years and the emergence of nanotechnology as a distinct field. For these historically-produced and long-used materials, there is no reason–and indeed no suggestion by anyone in the literature–that such materials pose possible environmental, health, or safety risks. These historical materials include carbon black and a variety of materials used in food production, including the production of homogenized milk and mayonnaise. Although some or all of these materials might be excluded by a definition of nanomaterials that requires that nanomaterials have been "engineered," as the JRC Report suggests that is not obviously the case; so an explicit exclusion for materials produced prior to a plausible date (e.g. 1980 or 1990) might be preferable. JRC REPORT, *supra* note 13, at 4.2.6.

29. *Cf.* Definition of Nanomaterial, *supra* note 1.

30. *Id.* The Danish Ministry of Environment definition also includes no reference to the concepts of intentionality/engineered/manufactured, although even that definition suggests that nanomaterials must be "produced" or "made" as opposed to being naturally occurring. JRC REPORT, *supra* note 13, at 3.3.3.

31. *See* Definition of Nanomaterial, *supra* note 1.

alternative to the objective, physical approach would be an approach that defines nanomaterials based on whether or how much they exhibit novel properties associated with having one or more nano dimensions. This "novel properties" approach might be regarded as more subjective because it is, to an extent, subjective what constitutes a "novel" property in any particular case. As one commentator explained:

> While the "novel properties" concept rests at the center of world-wide interest in nanotechnology, it also presents materials characterization and regulatory problems. What exactly are these "novel properties," how are they defined, are they consistent from one type of nanomaterial to the next, do they vary in intensity under certain circumstances, and are they measurable and capable of standardization? If not, how are we going to handle this aspect of the definition when it comes to materials characterization projects and/or regulations? Scientists–not lawyers–will have to answer these questions, of course.[32]

This subjectivity could allow manufacturers to plausibly claim that they did not know certain materials qualify as nanomaterials, and hence could allow them to refrain from disclosing those materials to regulators. The possibility of nondisclosure on the part of manufacturers is heightened by the fact that the subjective approach also requires a great deal of information about the material—information about how the material "behaves" in different contexts—that most often is unavailable to regulators and the broader public. Conversely, subjectivity creates the possibility that manufacturers will lack the notice they deserve *ex ante*, when they are developing materials and/or products, that they will be subject to the regulatory definition of nanomaterials and any attendant regulatory requirements.

The attraction of a subjective approach is that it ties the definition more closely to a main source of risks associated with the nanoscale, that is, that otherwise benign materials may behave in novel ways that require regulatory consideration when those materials are configured at the nanoscale. Because novel

32. John C. Monica, Jr., *"Novel Properties" Dilemma*, NANO L. REP., Mar. 6, 2007, http://www.nanolaw report.com/2007/03/#axzz2IitL7abh.

properties are directly tied to one of the main reasons we believe nanomaterials may pose risks to human health and the environment, a definition that directly references novel properties might be thought to be more functionally related to the animating goals of defining nanomaterials and, in that sense, less mechanical and more sophisticated than the objective, physical approach.

We observe two approaches in proposed regulatory definitions of nanomaterials. In one approach, only objective, physical criteria are referenced. This is the approach most definitive of the European Commission, which has expressly recommended that only size be considered in defining what is a nanomaterial.[33] In a proposal regarding nanomaterials in pesticides under FIFRA, EPA opted for an objective, physical approach, explaining that, in its view, relying on "novel properties" in the context of a regulatory definition was unworkable:

> These elements[, novel properties and unconventional behavior of materials,] do not readily work in a regulatory context because of the high degree of subjectivity involved with interpreting such phrases as "unique or novel properties" or "manufactured or engineered to take advantage of these properties." Moreover, the contribution of these subjective elements to risk has not been established. Instead, OPP will focus on more objective criteria in describing when information about a "nanoscale material" in a pesticide product may be relevant to determining whether the product has an unreasonable adverse environmental effect. Specifically, such information may be relevant in this context when the active or inert ingredient and any component parts thereof is intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers, regardless of the aggregation or agglomeration state of the final material.[34]

33. Definition of Nanomaterial, *supra* note 1.

34. Policies Concerning Products Containing Nanoscale Materials, 76 Fed. Reg. 35383-01, 35387 (proposed June 17, 2011) (to be codified at 40 C.F.R. ch. 1). In October 2010, EPA submitted a proposed TSCA revision to OMB that also reportedly follows an objective, physical approach. Under this proposal, any chemical substance from 1 to 100 nanometers will be subject to TSCA's

In the second approach, there is an objective, physical definition of nanomaterial and then a second, subjective, functional definition that applies even when the objective, physical criteria are inapplicable.[35] This approach, a kind of catch-all approach, is what Canada's regulators have proposed. According to the Canadian definition, any manufactured substance or product and any component material, ingredient, device, or structure is a nanomaterial if "[i]t is at or within the nanoscale in at least one external dimension [1 to 100 nanometers]" or "[i]t is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena," where "nanoscale properties/phenomena" "means properties which are attributable to size and their effects," and that "are distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material. . . ."[36] Although this definition employs "nanoscale properties" instead of novel properties, it raises the same question of subjectivity, that is, is there and can there be a firm guide telling a manufacturer in a specific case whether its material has or does not have a nanoscale property?

In theory, one could imagine a third approach—one in which nanomaterials are solely defined by whether they exhibit novel properties associated with dimension or size, regardless of their actual size. Some might think such a subjective, although appealingly functional, approach would be unworkable, for reasons already suggested; and indeed one might argue that in practice this approach would mean no actual definition of nanomaterials as a distinct category. While no agency has proposed this approach, a Whitehouse/OMB guidance document comes close to suggesting as much: "[f]or oversight and regulation . . . the critical issue is whether and how . . . altered properties

Significant New Use Rule (SNUR). "This regulatory revision treats the nanomaterial as a new chemical and requires submission of data to EPA at least 90 days prior to commencing manufacture of these types of materials." U.S. EPA, OFFICE OF INSPECTOR GEN., EPA NEEDS TO MANAGE NANOMATERIAL RISKS MORE EFFECTIVELY: REP. NO. 12-P-0162, 4 (2011), *available at* http://www.epa.gov/oig/ reports/2012/20121229-12-P-0162.pdf.

35. *See* HEALTH CANADA, POLICY STATEMENT ON HEALTH CANADA'S WORKING DEFINITION FOR NANOMATERIAL (2011), *available at* http://www.hc-sc.gc.ca/sr-sr/pubs/nano/ pol-eng.php.

36. *Id.*

and phenomena emerging at the nanoscale create or alter the risks and benefits of a specific application," and thus "[a] focus on novel properties and phenomena observed in nanomaterials may ultimately be more useful than a categorical definition based on size alone."[37]

D. How Small and How Many Particles

The final debate among the proposed regulatory definitions of nanomaterials has to do with the exact specifications for size criteria. As already noted, one dimension of 1 to 100 nanometers in length is a conventional scientific definition of the nanoscale, and almost all proposed regulatory definitions incorporate that scale. However, a few proposed definitions contemplate a scale of up to 1,000 nanometers.[38] There would appear to be no inherent significance in 100 nanometers as a defining upper limit, but it is not obvious that there is anything inherently significant about the largest upper figure that has been suggested, 1,000 nanometers, either. There is some suggestion in the literature that we see the most novel properties at a scale well below 100 nanometers,[39] but an essential truth of this whole area is that there is a great deal unknown, and there is a great deal of

37. JOHN P. HOLDEN ET AL., POLICY PRINCIPLES IN THE U.S. DECISION-MAKING CONCERNING REGULATION AND OVERSIGHT OF APPLICATIONS OF NANOTECHNOLOGY AND NANOMATERIALS (2011), *available at* http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-/nanotechnology-regulation-and-oversight principles.pdf.

38. The JCR Report suggests an upper limit of 1,000 nm. The National Organics Standards Board Materials Committee, convened under the authority of the U.S. Department of Agriculture, in a recent statement (February 25, 2010) has suggested an upper limit of 300 nm. In 2010, the U.K. House of Lords Science and Technology Committee suggested 1,000 nm. SCI. & TECH. COMM., NANOTECHNOLOGIES AND FOOD, 2010, H.L. 22-I, ¶ 5(24) (U.K.). The California Safer Consumer Product Alternatives Act similarly proposes a nanoscale between 1-1,000 nanometers. For a discussion of the arguments and suggestions for a 1,000 upper threshold, see CANADA ENVTL. LAW ASS'N, RESPONSE TO INTERIM STATEMENT ON HEALTH: CANADA'S WORKING DEFINITION FOR NANOMATERIALS 8-9 (2010), *available at* http://www.cela.ca/publications/response-interim-policy-statement-nano materials.

39. Mélanie Auffan et al., *Toward a Definition of Inorganic Nanoparticles From an Environmental, Health and Safety Perspective*, 4 NATURE NANOTECHNOLOGY 634 (2009).

diversity and difference among particles and materials even of the same rough size.

A related debate is whether "nanomaterials" should include any material that includes any nanoparticle or only materials including some percentage of nanoparticles. Many substances contain particles of a range of sizes, some of which are arguably "nano," and many of which are not. Most of the proposed regulatory definitions to date seem to suggest that a material or substance containing any nanoparticle is itself a nanomaterial, but the European Commission recommends that a material be classified as a nanomaterial only if fifty percent or more of its particles are nanoscale.[40] But even the Commission qualifies this limitation by providing that a threshold lower than fifty percent may be appropriate on a case-by-case basis.[41]

E. Likely Exposure As Part of The Definitions

Regulators may never know exactly how dangerous or not dangerous any given nanomaterial (however defined) may be for human beings who come into contact with the material. But even for materials where there is genuine uncertainty as to how the substance will behave, it may be possible to at least estimate how many people could be adversely affected assuming, on a precautionary basis, that the material can adversely affect human health. Some nanomaterials are and will be used in food or toothpaste or nasal sprays, all of which involve intense human exposure to potentially millions of people, including vulnerable populations. Other materials will be used in (for example) tennis rackets and tires, both of which involve less intense human exposure, and still others will be used in medical treatments that are designed for use on only a few hundred people per year. From a precautionary perspective, in the face of uncertainty about each particular material, it might make sense to define nanomaterials more expansively in realms where intense, mass human exposure is very likely and less expansively where that is less likely. Thus,

40. Definition of Nanomaterial, *supra* note 1.

41. *Id.* ("In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%.").

it might make sense for the definition of nanomaterials for foods regulated by the FDA and pesticides regulated under FIFRA to extend up to 1,000 nanometers.

By contrast, when a material is not being produced for use in a mass market product and/or is intended only for use in an arena of relatively limited and controlled human exposure, there may be an argument for the application of a *de minimis* risk-based exclusion from an otherwise applicable regulatory definition of nanomaterials. A nanomaterial that is being produced in very tiny amounts for use in the construction of equipment for outer space, for example, could fall in such a *de minimis* exception.

However, there are considerable operational difficulties in implementing an approach that provides for an expansive regulatory definition based on likely scope of human exposure or that allows for a *de minimis* exception based on very limited likely exposure. For one thing, a material that is initially not intended for mass marketing or human consumption could be re-directed to such uses at a later date; moreover, materials can come into close human contact through the process of disposal and subsequent absorption into the environment (e.g., via leaching into a drinking water supply).[42] There are many possible pathways of exposure with nanomaterials, and there may be no way to trace pathways in the environment because of the lack of technology to identify and track such small materials.

A proliferation of different definitions of nanomaterials based on likely exposure scenarios also works against facilitating communication and coordination as among different agencies and offices. At the same time, the fact that most attention to regulatory definitions of nanomaterials to date has centered around food, the food chain, and cosmetics implicitly affirms the view that likelihood of mass human exposure is a highly relevant variable.[43]

42. U.S. EPA, *supra* note 34, at 2 ("there also exists the potential for exposures to nanomaterials during product manufacturing, use and/or at the end of the product life cycle through recycling, landfills, and waste incineration.").

43. The Whitehouse/OMB guidance seems to suggest incorporating exposure scenarios into regulatory definitions, however. *See* HOLDEN ET AL., *supra* note 37. In other work, I argue that exposure should factor in regulatory definition. *See*

IV. A REGULATORY DEFINITION IS NECESSARY

Before addressing what kind of definition agencies should adopt for nanomaterials, it is important first to explain why definitions are necessary and not, as Maynard argues, counterproductive. Maynard is right that any regulatory definition or definitions of nanomaterials will include some materials that pose real risk and others that do not. But that is not a reason to avoid regulatory definitions of nanomaterials because defining is the first, not the last, step in a process of considering what regulatory requirements should apply. An agency could define a universe of (say) 10,000 nanomaterials and then proceed to identify only 1,000 that warrant testing or additional testing, and then based on that testing, apply labeling or warning requirements to only a handful of the original 10,000.

Maynard seems to suggest that once materials receive designation as nanomaterials, they will acquire a taint in the public imagination, and substantive and perhaps unreasonable regulation of all of them will follow as a political and social imperative.[44] But the opposite is likely true. Public concern about nanotechnology and nanomaterials is likely to be assuaged if the public (and in particular relevant NGOs that help shape public opinion) have reason to think that agencies are taking a close look at nanotechnology and nanomaterials, even if that means the agencies' close look in most cases results in no further action. And the public may not credit agencies as taking a close look if agencies lack even a definition of nanomaterials. Indeed, it is hard to see how not defining nanomaterials will increase public trust that the government is addressing present and potential risks posed by nanomaterials.[45]

Maynard also suggests that regulatory definitions of nanomaterials might result in regulators not taking a close look

THE NANOTECHNOLOGY CHALLENGE: CREATING LEGAL INSTITUTIONS FOR UNCERTAIN RISKS (David A. Dana ed., 2012).

44. Maynard, *supra* note 26.

45. *See* Jeremy Warren, *The EU Definition of Nanomaterials – Getting What You Wished For*, LABORATORY NEWS, June 12, 2012, http://www.labnews.co.uk/features/eu-definition-nanomaterials-%E2%80%93-wished-for/ ("To gain trust nanotechnology needs a regulatory framework – but before this can happen we need to know one thing – just what is a nanomaterial.").

at substances or materials outside the definition.[46] This point, however, is better formulated as a critique of too narrow or inflexible a definition of nanomaterials than as support for having no definition at all. Moreover, any regulatory effort at ascertaining risk and response has to start somewhere and cannot start everywhere; defining nanomaterials, even defining them inflexibly by size or largely by size, may be a reasonable starting point and lay the ground for exploration of risks posed by materials that are too large or otherwise fall outside the definition. We see exactly that in the arena of particulate matter emissions, where EPA has moved beyond regulation of larger particulate matter to include smaller or fine particulate matter, as the agency learned more about these emissions.

The need for regulatory definitions is also related to the need to facilitate communication and learning within an agency and among agencies. A working definition helps an agency or agencies identify and build bridges among staff working on issues or with regard to materials that implicate the nanoscale. Because there are in fact some common issues and potential for shared learning about the nanoscale, such identification is important. Indeed, one of the EPA Inspector General's (I.G.) criticisms of the agency's nanotechnology/nanomaterials efforts to date is that there has been a lack of coordination and sharing of information.[47] As the I.G. Report explained:

> EPA does not have an Agency-wide, formal process to disseminate manufacturer data. . . . [I]nformation sharing is not facilitated by a formal process; rather, it depends on personal relationships between program staff. . . . Coordinated sharing of nanomaterial data call information will also be important if additional regulatory actions become necessary. . . . Because of the growing number of nanomaterial products entering the marketplace . . . it will become increasingly necessary for these program offices to share information and coordinate their efforts.[48]

46. Maynard, *supra* note 26.
47. U.S. EPA, *supra* note 34, at 9.
48. *Id.* at 9-10.

Having clear regulatory definitions of nanomaterials cannot create coordination and information-sharing, but it seems reasonable to assume it can help. The larger point is that definitions are always imperfect but they nonetheless are important for establishing a discourse.

A. Agency Definitions Should Be Information-Forcing

That agencies are not operating in some idealized space with respect to nanomaterials was underscored by the recent EPA Inspector General report:

> At the time of our review, EPA did not have sufficient information or processes to effectively manage the human health and environmental risks of nanomaterials. EPA does not have a formal process to coordinate the dissemination and utilization of nanomaterial information or communicate nanomaterial risks. . . . [T]echnological limitations inhibit nanomaterial detection in the environment, and a reliance on industry data impedes effective nanomaterial management.[49]

Regulators do not even have a ready way of knowing what nanomaterials or arguable nanomaterials are being produced and/or how they are being deployed.[50] Nanoparticles are not readily visible, and they are not typically listed as distinct ingredients even on packaged consumer products.[51] Moreover, even when regulators have some idea of the components of a given product, they may have very little information with which to assess and evaluate those components, given the newness and complexity of nanotechnology. Further, because there are an almost infinite variety of any nanoscale materials and because the nanotechnology industry and nanoscale materials are fast evolving, it may be impossible for even the most heroic of

49. *Id.* at 9.

50. Robin Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J.L. MED. & ETHICS 704, 707 (2006).

51. *Nanoparticles Found in 10 Top Brand Cosmetics*, FRIENDS OF THE EARTH, http://nano.foe.org.au/nanoparticles-found-10-top-brand-cosmetics (last visited Nov. 15, 2012).

regulators to keep up.[52] Regulators on their own, without the assistance of industry, cannot have the information they need to grasp the current state of play in nanotechnology.

The relevant question then is how can agency definitions of "nanomaterials" be structured so as to maximize the amount of relevant information they receive regarding nanomaterials and the possible risks and risks posed by nanomaterials? Given the lack of information on the part of regulators regarding nanomaterials, regulatory definitions cannot describe the contours of risks but rather must be a means of generating the information needed to assess the contours of risks.

This question calls for a distinction between two kinds of information. The first is information that industry has or can readily obtain regarding nanoscale materials it is making or using, such as the size of those materials or their chemical identity. The second is information that would require industry to make some significant investment to generate information regarding these materials that could be helpful to an understanding of the risks posed by or not posed by such materials. The latter category, in many cases, will include precise assessments of the novelty of behavior of the nanomaterials in relevant contexts, which itself may require tests for effects on human health and the environment. While some companies may perform such testing in the absence of specific regulatory requirements, there are good reasons to postulate that many companies do not.

Industry has no strong and consistent incentive to voluntarily provide regulators with all the relevant information it possesses. Doing so, industry understands, can lead to costly new requirements or even product prohibitions. That may explain why so little information appears to have been produced in response to EPA's Voluntary Stewardship program for nanomaterials.[53] And, outside the context of nanomaterials,

52. *Nanotechnology Market Forecast to 2014*, MARKET WATCH (Oct. 22, 2012, 9:11 AM), http://www.marketwatch.com/story/nanotechnology-market-forecast-to-2014-2012-10-22.

53. *See EPA's Voluntary Reporting Program Fails To Deliver Data Needed To Determine Safety Of Nanomaterials, Report Shows,* ENVTL. DEFENSE FUND (Jan. 13, 2009), http://www.edf.org/news/epas-voluntary-reporting-program-fails-deliver-data-needed-determine-safety-nanomaterials-repor (explaining that EPA

there is *not* a long history or clear record of industry actors making voluntary disclosures to regulators: tobacco companies certainly did not disclose the information they had that was relevant to links to cancer until they absolutely were required to do so. Thus, although the FDA apparently contemplates producers of FDA-regulated products to consult with them in an ongoing and volitional way about nanoscale components in their products, there are reasons to question whether businesses will initiate such consultations in the FDA context. Voluntary consultation, moreover, seems even more unlikely in contexts where businesses know they are subject to less precautionary statutory and regulatory authorities than those under which the FDA operates.

Moreover, industry not only has incentives not to offer up information to regulators it has or could readily obtain, it also has reasons not to invest in developing additional information that would be relevant to risk assessments by regulators.[54] There are strong incentives for industry not to know about potentially risky aspects of the materials and/or products they make. Knowing about risk requires a research investment by industry, and any one company that makes that investment is assuming higher costs than its competitors who avoid those costs. Moreover, the investment may only result in greater tort liability down the road, as well as regulatory penalties for knowingly engaging in dangerous conduct.[55] Ignorance, in other words, is sometimes and perhaps many times rational.

Ideally, a regulatory definition would do two things. First, it would effectively compel industry to disclose the information it already has regarding a set of materials at issue. Second, the definition would combat the phenomenon of intentional industry

has acknowledged that its voluntary approach has yielded "only limited information on a small fraction of the hundreds of potentially toxic nanomaterials").

54. *See* Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1670-77 (2004); *see also* Wendy E. Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 693-95 (2007).

55. *See* David A. Dana, *When Less Liability May Mean More Precaution: The Case of Nanomaterials*, 28 UCLA J. ENVTL. L. & POL'Y 153, 170 (2010).

ignorance by providing an incentive for industry to generate additional relevant information and to share that information with regulators.

Regulatory definitions that do not contain relatively objective criteria, such as particle size, and that instead only track whether a material was engineered to behave in "novel" ways, may well not meet these objectives. Flexible, subjective, functional definitions of nanomaterials tied to whether a material displays novel properties related to size leave enough room for industry not to disclose what it knows to regulators because what is covered under such definitions is contestable. "Wiggle room" will result in the avoidance of disclosure. EPA's recent endorsement of objective criteria, from the perspective of the realities of behavior on the part of regulated entities (at least in the United States context), makes sense. Functional, subjective definitions work best under assumptions of eager compliance and openness that have little grounding in actual practice.

At the same time, objective definitions tied to size or other similar criteria, while likely to produce information regarding which products contain nanomaterials based on these criteria, are not likely by themselves to encourage industry to disclose what it knows about subjective matters such as "novel properties" or to invest in obtaining more information about novel properties. Industry needs an incentive to provide and generate information that otherwise would offer them no benefit.

One way to incentivize the production and disclosure of such information would be to add to the definition of nanomaterials a provision whereby materials that would be included under a size criteria could be excluded if industry could demonstrate both that (1) the material, despite its small size, will not be deployed in a context where the size itself could cause harm, and (2) the material is not characterized by novel properties that could result in human health or ecological harm. By rewarding industry with exclusion from the realm of regulatory definitions and possible attendant regulatory costs, a definition of nanomaterials similar to the aforementioned one can address the disincentives for industry research that are a central problem in regulation. Even if only some industry participants choose to engage in such a dialogue with regulators, regulators could learn a great deal

about nanotechnology and novel properties that they could apply broadly to their regulatory efforts.[56]

B. Regulatory Definitions Must Take Account of Information Staleness

The whole enterprise of regulating nanotechnology—and hence the included enterprise of defining nanomaterials for regulatory purposes—ideally would be an exercise in "adaptive management," or management that continually adapts to take account of new information and new insights. It is easy to call for adaptive management; no one supports non-adaptive management. But adaptive management always should be understood as a goal that requires specific encouragement and support. Regulated entities need some stability to operate, and stability means some periods of relative non-adaptation; and regulators, perpetually overworked and overburdened, and at least somewhat removed from developments in science and industry, may not engage in even periodic adaptation unless institutional structures are in place to encourage them to do so.[57] Just as industry must be encouraged to provide and generate information, regulators must be encouraged to seek out and take account of new information on an ongoing basis and use that new information to inform regulatory definitions as well as substantive regulatory requirements.

One institutional means of achieving this goal would be an agency commitment, ideally formalized in an agency regulation, to issue a review of its regulatory definition no less than once every five years, and in which the agency would be required to explain why it was or was not changing the current regulatory definition at a minimum of five year intervals. The process of putting out such a review for notice and comment would help

56. Participation by a few companies might prompt broader participation because companies would not want the information provided by participants used against them and their products, and would prefer to have a more active role in shaping the factual conclusions drawn by the agency. They also might not want to appear less cooperative than other participants.

57. On regulatory inertia, see David E. Adelman & Kirsten H. Engel, *Adaptive Federalism: The Case Against Reallocating Environmental Regulatory Authority*, 92 MINN. L. REV. 1796, 1826 (2008).

focus debate on developments in nanotechnology that might justify changes in the regulatory definition of nanomaterials.[58]

Another way of achieving ongoing adaptation would be to allow citizens and regulated entities at any time to petition an agency to include a material or exclude a material, and the agency could be required to respond to such petitions within a reasonable time. While an allowance for petitions carries with it the risk that scarce agency resources will be absorbed by petitions instead of potentially more important tasks, in terms of health and the environment, an allowance for petitions fosters the generation of more data and serves the important values of public participation and transparency.[59]

One other possible institutional means of achieving ongoing adaptation would be the creation of an advisory board to inform an agency regarding relevant changes in the nanotechnology industry. If the advisory board was composed of industry, academic, and NGO representatives, as might be highly desirable to maximize both informational inputs and enhance public participation, one issue would be whether such an advisory board could achieve a consensus. Another issue would be whether the advisory board's recommendations would have any influence on the agency. If the agency were required to review regulatory definitions every five years and explain why changes were not needed, the advisory board could be called on to participate in the review process as part of the governing procedures and the agency would thus be required to account for the input of the advisory board.

C. The Value of Information Production is Undermined by Excessive Confidentiality Restrictions

An information-forcing regulatory definition of nanomaterials, and institutional mechanisms to encourage

58. The Clean Air Act has provisions that operate in this way. *See* 42 U.S.C §§ 7408, 7409, 7429 (2012).

59. *See generally* Jennifer Kuzma et al., *Evaluating Oversight Systems for Emerging Technology: A Case Study of Genetically Engineered Organisms*, 37 J.L. MED. & ETHICS 546 (2009) (discussing the link between components of the system of regulatory oversight and public confidence regarding emerging technologies).

ongoing collection of information and reformulation of the regulatory definition, only work if agencies use the information they receive to the greatest effect. The designation of information received by an agency as confidential business information works against that objective in two ways. First, the designations make it more difficult for the agency to obtain both internal, and even more so, external assessments of the significance of the information. Second, and relatedly, the designations make it difficult for external stakeholders to confirm that the agency is doing its job in the ways it should, and not ignoring risks due to negligence or undue external pressure. If external stakeholders cannot review the data an agency has obtained, the stakeholders cannot provide nearly as useful input as otherwise would be possible, and cannot provide meaningful critiques of the agency that might prompt action. Under current practice at EPA under TSCA, industry designations of information as confidential business information have been taken entirely at face value. The submitting company need not explain why it is claiming the designation or provide reasons why the designation is appropriate.[60] The result, by all accounts, is a massive over-claiming of the confidential business information designation.[61] While this is not a problem in any way limited to nanomaterials, nanomaterials are a good place to start in rectifying it.

V. CONCLUSION

The debate over defining nanomaterials for regulatory purposes centers on the basic issue of whether a definition is

60. *See* U.S. EPA, *supra* note 34, at 5-6 (explaining that the TSCA program, under which EPA plans to regulate nanomaterials, is "limited by . . . claims of confidential business information (CBI) on industry data submissions . . . up to 90 percent of TSCA premanufacture notices contain claims of CBI. Excessive CBI designations inhibit independent peer reviews, oversight by external parties, and information sharing across EPA offices.").

61. *See, e.g.*, *Assessing the Effectiveness of U.S. Chemical Safety Laws: Hearing Before the S. Comm. on Env't & Pub. Works S. Comm. on Superfund, Toxics & Envtl. Health*, 112th Cong. (2011) (statement of Frances Beinecke, President, Natural Resources Defense Council, Inc.) ("TSCA's Confidential Business Information (CBI) provisions . . . allows [*sic*] companies to make nearly unlimited claims of CBI, without requiring any upfront justification or EPA review, and without any date of expiration or requirement for periodic renewal and justification of such claims.").

advisable or not, and whether any such definition should be based on relatively objective physical criteria or more subjective functional ones. This Article argues that a definition is necessary, and that the definition or definitions should be information-forcing. The definition should be structured so as to require and encourage industry to generate and disclose relevant information. The relevant regulatory or statutory provisions should also encourage regulators to continue to seek and evaluate new information and use that information to update the regulatory definitions. This approach requires that the regulatory definition include relatively objective physical criteria, but would also provide for the exclusions from or additions to the category of nanomaterials based on functional considerations.

Getting regulatory definitions right is a key step in creating an effective regulatory framework for assessing and managing the risks posed by nanomaterials, which in turn is essential to realizing the maximum social benefit of the nanotechnology revolution.