



White House Office of Science and Technology Policy (OSTP)
National Science and Technology Council
National Nanoscale Science Engineering and Technology (NSET) Subcommittee

Request For Information (RFI): 2021 National Nanotechnology Initiative (NNI) Strategic Plan¹

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Submitted Electronically to NNIStrategicPlanning@nnco.nano.gov

The Institute for Agriculture and Trade Policy (IATP) is pleased to have the opportunity to provide information to assist the NSET Subcommittee in the development of the 2021 draft Strategic Plan. IATP commented on the previous draft Strategic Plan² and responded to the OSTP “Grand Challenges” for nanotechnology.³ We have been the beneficiary of participation in several excellent NNI sponsored webinars and workshops, a few of which we have reported on.⁴

Responsible development of nanotechnology

Of the many questions posed in the RFI, IATP will first respond to that concerning the NNI goal of the “responsible development of nanotechnology.” The RFI asks, “As concepts surrounding

¹ <https://www.govinfo.gov/content/pkg/FR-2020-10-13/pdf/2020-22556.pdf>

² Steve Suppan, “Comment on the National Nanotechnology Initiative Draft Strategic Plan,” Institute for Agriculture and Trade Policy, December 20, 2013. <http://www.iatp.org/documents/comment-on-the-national-nanotechnology-initiative-nni-draft-strategic-plan>

³ <http://www.iatp.org/files/OSTP%20Nanotechnology%20Grand%20Challenges.pdf>

⁴ E.g., Steve Suppan, “Future of U.S. federal nanotechnology: ‘safe by design’ product commercialization,” August 29, 2019,” Institute for Agriculture and Trade Policy, <https://www.iatp.org/blog/201908/future-us-federal-nanotechnology-safe-design-product-commercialization>; “Supporting science to advance the responsible development of nanotechnology,” Institute for Agriculture and Trade Policy, February 23, 2017, <https://www.iatp.org/blog/201703/supporting-science-advance-responsible-development-nanotechnology>; “Nano. Inc.? There’s been an accident on Highway 15,” Institute for Agriculture and Trade Policy, July 28, 2016.

<http://www.iatp.org/files/OSTP%20Nanotechnology%20Grand%20Challenges.pdf>; and Suppan, “Nanotechnology without the hype,” Institute for Agriculture and Trade Policy, September 29, 2014.

<http://www.iatp.org/blog/201409/nanotechnology-without-the-hype>

responsible development have evolved over the past twenty years, what factors may contribute to the responsible development of nanotechnology going forward?”

In the 2016 NNI Strategic Plan, an important objective to realizing responsible development was to “Support the creation of a comprehensive knowledge base for evaluation of the potential risks and benefits of nanotechnology to the environment and to human health and safety.” (Goal 4.1, p. 22) The National Nanotechnology Coordinating Office (NNCO) has organized or hosted dozens of activities over the past five years in support of this goal and associated sub-goals. Perhaps the most ambitious of these activities is the U.S. EU Communities of Research work on a nano-informatics platform to standardize and systematize the reporting of nanotechnology and nano-science research. The application of nano-informatics data and methodology to EHS risk assessment and to “safer by design capabilities” has been demonstrated⁵ and should become an objective of the 2021 Strategic Plan. How can the nano-informatics platforms, built thus far on a budgetary shoestring and the pro bono contributions of mostly academic scientists, be scaled up for use across NNI agencies?

One of the benefits of the process of developing nano-informatics platforms is the interdisciplinary convergence that has been an NNI hallmark. However, to scale up the building and application of such platforms for EHS application, a more comprehensive framework is needed to formulate NNI consensus nano-EHS questions and technically and financially support EHS research beyond what is accessed and standardized in the nano-informatic categories. NNI agencies have not published a collective EHS strategy since 2011. The draft Strategic Plan should commit NNI agencies to review the EHS literature of the past decade towards contributing to an EHS Research Strategy that anticipates EHS research and associated infrastructure that will be needed over the next decade.

Although NNI continues to publish reports from its excellent EHS workshops and to present a broad array of EHS studies in its webinar series, the 2011 NNI EHS Research Strategy has not been reviewed since 2014.⁶ Some individual NNI agencies have published summaries of their EHS research.⁷ However, the convergence of NNI agencies to develop a research strategy for the next decade would have the budgetary advantage of reducing duplicative research and infrastructure needs and expense.

A new NNI EHS Research Strategy would include a review of what was accomplished and what was intended but not accomplished in federally funded EHS research since the 2014 review of

⁵ Christine Ogilvie Hendren and Fred Klaessig, “A Case Study in Convergence and Team Science,” National Nanotechnology Coordinating Office NanoEHS Webinar Series, November 12, 2019. https://www.nano.gov/sites/default/files/NNNIwebinar-Nanoinformatics-Convergence-TeamSci-Nov2019_final.pdf

⁶ <https://www.nano.gov/node/1157>

⁷ E.g., Debra L. Kaiser and Vincent A. Hackley, “NIST Nanotechnology Environmental, Health and Safety Research, 2009-2016,” National Institute of Standards and Technology, NIST Special Publication 1233, November 2018. <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1233.pdf>

the 2011 EHS Research Strategy. NNI EHS research funds have been historically concentrated in a few agencies, above all Health and Human Services, National Science Foundation and Environmental Protection Agency⁸, so a survey of EHS research in the NNI agencies would not show uniform scale of results. However, all NNI agencies might benefit from a process to identify EHS research accomplishments and needs. One way to focus a new Strategy would be to determine any EHS research needs, including any new infrastructure, for achieving current and prospective NNI Signature Initiatives. Because each Signature Initiative involves research and development in more than one agency, developing EHS Research Strategy for those Initiatives could engage multiples agencies.

IATP strongly prefers that a new NNI EHS Research Strategy be a stand-alone process and a stand-alone document. However, if the NSET Subcommittee decides that the objectives of a new EHS Research Strategy should become part of the 2021 Strategic Plan, we urge the NSET Subcommittee to propose launching a separate NNI EHS Research Strategy by the end of 2021.

The “Supporting Information for the NNI Strategic Planning” identifies “potential ethical legal and societal implications” (ELSI) of nanotechnology as crucial, along with EHS research, to achieving the goal of “responsible development.” However, there are no budget lines or program components for ELSI research in the “NNI Supplement to the President’s 2021 Budget.” IATP has not reviewed all the past NNI budgets, but to judge by the titles of NNI workshops dating back to 2003, there have been no ELSI workshops and just one on “public engagement” (2012) that could concern societal implications.

If the 2021 Strategic Plan is to retain the “responsible development” goal, the NSET Subcommittee should outline how ELSI research has been used and might be used in the future to achieve that and other Strategic Plan goals. The NSET Subcommittee could propose that the NNI organize one or more workshops to consider how ELSI research could advance realization of the NNI Signature Initiatives. For example, regarding the Food and Agriculture Signature Initiative, ELSI researchers could evaluate industry consultations with the Food and Drug Administration concerning FDA voluntary guidance documents on engineered nanomaterials in food, food ingredients and food contact surfaces.⁹ In its most recent nanotechnology report, FDA explains that it applies a “science-based product-focused regulatory policy” to regulating nanotechnology products.¹⁰ A sample research question: have such consultations about specific products resulted in responsible development of food related products that incorporate engineered nanoscale materials? Or regarding the Nano-biosensor Initiative, ELSI researchers

⁸ E.g., “The Nanotechnology Initiative: Supplement to the President’s 2021 Budget,” October 2020. Table 2: 2019 Actual Agency Investments by Program Component Area, at 6.

<https://www.nano.gov/sites/default/files/NNI-FY21-Budget-Supplement.pdf>

⁹ <https://www.fda.gov/science-research/nanotechnology-programs-fda/nanotechnology-guidance-documents>

¹⁰ “Nanotechnology—Over a Decade of Progress and Innovation,” Food and Drug Administration, July 2020, at 6. <https://www.fda.gov/media/140395/download>

might report on ethical and legal issues arising from the development and use of such sensors, e.g., concerning how and when sensor-generated data should be anonymized.

If the NSET Subcommittee decides that ELSI research is no longer necessary to achieving the “responsible development” goal, it should state so clearly and explain the reasons in support of such a determination.

Speeding up the commercialization of nanotechnology products

The Quadrennial Review of the National Nanotechnology Initiative by a committee of the National Academies of Science Engineering and Medicine has recommended to the NSET Subcommittee the continuation of the NNI and its reorganization to accelerate the commercialization of nanotechnology products.¹¹ Although the National Academies report criticizes NNI’s performance in achieving its first three goals, the report authors praise the NNI achievements: “on Goal 4 the committee considers that the NNI has performed exceptionally well and is recognized internationally for its leadership in responsible nanotechnology development and for leveraging international collaborations, although agency engagement appears to be waning.” (p. 3) As the NSET Subcommittee considers the recommendations of the National Academies report, IATP advises it to support strengthening the international collaborations that have been crucial to U.S. leadership in responsible nanotechnology development. The Subcommittee should not propose that achievement of all four NNI goals will be realized by applying an industry Return on Investment analysis as the final arbiter of the success of NNI collaborations with and support for industry and entrepreneurial academics. Among the questions for the Subcommittee to consider is how the advocacy for accelerating commercialization may impact NNI agencies’ already “waning engagement” in responsible development.

The RFI poses several questions that bear on the recommendations that the NNI be reconfigured to direct more public funds to programs to accelerate the “lab-to-market” delivery system. We select just two questions to answer:

What is your understanding of how the Federal Government has supported the nanotechnology community since the launch of the NNI?

How can the government engage effectively with stakeholders in industry and academia to advance nanotechnology research, development, and eventual commercialization?

What are some best practices for this kind of engagement?

It is not much of an exaggeration to say that researchers in the various science and engineering disciplines became the “nanotechnology community” because of the organizational, research and investment initiatives of the Federal Government. As is well known to the NSET

¹¹ National Academies of Sciences, Engineering, and Medicine 2020. A Quadrennial Review of the National Nanotechnology Initiative: Nanoscience, Applications, and Commercialization. Washington, D.C.: The National Academies Press, at 3-4. <https://doi.org/10.17226/25729>.

Subcommittee, the participating agencies of the NNI provide a huge range of public services to the “nanotechnology community,” ranging from building and leasing nanotechnology infrastructure; grant-making for nanoscience; EHS research workshops applicable to a broad range of products; federal agency product development transferred to the private sector for commercialization; regulatory, commercialization and patenting advice, particularly for small and medium scale enterprises; educational outreach, e.g., via science museums and secondary school STEM programs; and prototype manufacturing and testing services. In sum, the nanotechnology work of the NNI, the National Nanotechnology Coordinating Office (NNCO) and the grant-making agencies comprise a paradigm of what Mariana Mazzucato has called “the entrepreneurial state.”¹²

One of the problems of reorganizing the NNI to prioritize accelerating the commercialization of nanotechnology enabled products is that such a reorganization or reorientation may ignore or even disinvest in the public goods research, e.g., in infrastructure development, nano-informatics, EHS research or ELSI research that might result in commercialization delay. Governments have often invested in research that was too financially risky for most private enterprises to undertake, e.g., in the development of pharmaceuticals or cyber-infrastructure. NNI agencies should continue to perform this essential government function. Taxpayers financing NNI research should receive a public return on investment in the form of public goods, such as potable water and affordable medicines benefitting from robust EHS research. Nanotechnology return on investment should not be defined or calculated merely in terms of products brought to market, much less numbers of patents granted.

Mazzucato is one of the architects of the European Union’s Horizon 2020 research planning. She has proposed elsewhere that government research agencies need well-defined missions to be more entrepreneurial and innovative.¹³ A mission defined as simply to serve the needs of the private sector, as defined by the private sector, to facilitate product commercialization will serve neither the NNI agency nor the academic or industrial entrepreneur well. NNI agencies should not only maintain a robust research agenda as part of their mission, but also have a right to innovate, particularly in those areas of nanoscience and ERS research in which the private sector is unable or unwilling to invest.

A best practice for stakeholder engagement that NNCO and NNI agencies should scale up is hosting workshops at which products at an early stage of development are put to a manufacturing, value proposition and life cycle analysis tests that would take the product of out the lab and into its market and utilization environment. As far as IATP knows, the nano-biosensor is the most prominent example of NNI stakeholder engagement in both value

¹² Mariana Mazzucato, *The Entrepreneurial State: Debunking Public vs. Private Sector Myths*, (London, Anthem Press, 2014), 84-86.

¹³ João Medeiros, “The Economist Has a Plan to Fix Capitalism: It’s Time We All Listened,” *Wired* October 8, 2019. <https://www.wired.co.uk/article/mariana-mazzucato>

proposition analysis¹⁴ and the challenges of scaling up a product prototype in an industrial manufacturing process.¹⁵

NNI agencies, e.g., FDA and EPA, offered workshop presentations to stakeholders on “Navigating the Regulatory Process.” Another best practice would be for NNI agencies to share with product developers NNI agencies’ EHS and ELSI research to help product developers anticipate and avoid EHS risks, e.g., by taking advantage of NNI “safe by design” research.

Conclusion

IATP hopes that this response to the RFI will assist the NSET Subcommittee in drafting the Strategic Plan. We look forward to commenting on the draft Plan.

¹⁴ “NNI Sensor Fabrication, Integration and Commercialization Report,” September 11-12, 2014, at 4-8. https://www.nano.gov/sites/default/files/pub_resource/nnisensorsworkshopreport.pdf

¹⁵ “Nanosensor Manufacturing Workshop: Finding Better Paths to Products,” National Nanotechnology Initiative, June 13-14, 2017. https://www.nano.gov/sites/default/files/pub_resource/Nanosensor%20Manufacturing%20Workshop%20Summary.pdf