INSTITUTE FOR AGRICULTURE AND TRADE POLICY

Office of Science and Technology Policy (OSTP)

Request for Information: Nanotechnology-Inspired Grand Challenges for the Next Decade[i]

Submitted electronically: July 16, 2015

The Institute for Agriculture and Trade Policy (IATP), a 501 (c)(3) non-profit, non-governmental organization, is pleased to have the opportunity to comment on the above captioned Request for Information. If OSTP does not receive an adequate number of responses to its Request for Information (Request), we hope that it will consider extending the deadline for comment.

IATP has submitted comments to the Food and Drug Administration and Environmental Protection Agency concerning nanomaterials and nanotechnology applications affecting food, agriculture and the natural resource base of agriculture. We have participated in two National Nanotechnology Initiative co-sponsored workshops, including the July 7-8 workshop on Quantifying Exposure to Engineered Nanomaterials (QEEN).[ii]

General response

IATP agrees with the Request that "The need to more quickly and accurately determine whether engineered nanomaterials may pose a risk to the public and the environment continues to be a major challenge to the commercialization of nanotechnology for societal and public benefit" (Federal Register 80:16 (June 17, 2015), p. 34715). At the QEEN workshop, both regulatory and academic scientists discussed frankly and thoroughly the technical challenges of quantifying exposure to Engineered Nanoscale Materials (ENMs) in product matrices over the life cycle or "use phase" of those products. Some of these challenges could be met with increased funding of Environmental Health and Science (EHS) research and the infrastructure required for it not just in large university and government research facilities but in commercial toxicology laboratories. Several QEEN presenters commented on the budgetary constraints on creating what Dr. Lloyd Whitman of OSTP, in his introductory workshop remarks, called the "EHS ecosystem" required for commercialization of nanotechnology products.

However, several QEEN presenters identified an essential pre-requisite to the development of robust exposure data sets of ENMs in the human and environmental media of their use. Without the cooperation of nanotechnology and ENM product input

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developers, the research results of exposure studies of ENMs in their product matrices will not have regulatory validity, since exposure scientists are obtaining nanotechnology products for EHS research outside of a regulatory process. The challenge for OSTP and National Nanotechnology Initiative (NNI) funded agencies and researchers is to convince leading members of the nanotechnology industry that they must cooperate with regulatory and academic scientists by giving them nanotechnology enabled products and product data for independent and peer reviewed exposure research. None of the Grand Challenges exemplified in the Request can be realized safely, if they can be realized within the next decade, without the cooperation of industry to develop robust EHS exposure data about the ENMs in products and product inputs over the product life cycle.

Responses to some of the OSTP-posed questions in the Request

What is the audacious yet achievable goal proposed?

The OSTP should publish an Appendix to its March 4, 2011 "Principles for the Oversight and Regulation of Emerging Technologies."[iii] The Appendix would establish the terms and a deadline for Heads of Executive Departments and Agencies, particularly those with statutory EHS obligations, to develop a process for the mandatory submission of nanotechnology enabled products and ENM product inputs intended for commercialization to Department and Agency scientists for the purpose of developing robust exposure data about the product and/or input submitted over their use phase and/or life cycle. Department and Agency scientists would be able to delegate exposure assessment research to qualified exposure scientists and under terms stipulated by the Departments and Agencies, following the terms of the OSTP Appendix.

Why is it important for the Federal government and others to invest in solving this challenge?

If U.S. Departments and Agencies allow the commercialization of nanotechnology products without robust and peer-reviewed exposure data and data analysis, and such products cause harm or contribute to causing harm to public and environmental health or worker health and safety, the societal and public benefits of nanotechnology hoped for by OSTP will be severely truncated. For example, if baby rattles incorporating nano-silver are shown subsequent to commercialization to cause cancer in laboratory mice, the commercialization of nano-silver infused burn wound dressings could be retarded or even thwarted. These and other nanotechnology-enabled products have very different exposure periods and routes, but the public response to an industry that does not cooperate in developing and making public for peer review exposure data for the products they wish to commercialize may not discriminate among distinct product uses from an industry and regulatory process it does not trust.

What would success look like? How would you know that the challenge has been met?

In the best of all possible worlds, nanotechnology product developers and ENM manufacturers would realize that it is in their short-term and long-term commercial interests to submit products and ENM inputs intended for commercialization to Departments and Agencies for the development of exposure assessment databases. The QEEN exposure scientists stated on repeated occasions that they can generate terabytes of exposure data for specific ENMs in specific media. However, to accelerate the learning process to develop the high through-put predictive toxicology required by OSTP and the industry, the data from individual experiments must become part of a database that is readily searchable by regulatory and academic scientists. The aforementioned OSTP Appendix should instruct the National Nanotechnology Coordinating Office to convene NNI Departments and Agencies to meet with exposure scientists and discuss how to best organize and fund the creation of a comprehensive nanotechnology exposure studies database.

What would be potential solutions to the challenge and what intermediate steps and activities are necessary to develop those solutions?

One potential solution to the challenge of developing robust exposure data and a comprehensive exposure database for nanotechnology-enabled products and ENMs is to focus research and prototype product development in the NNI's nano-biosensor Signature Initiative towards EHS applications in regulatory science and practice. An investment banker presenting at the 2014 NNI workshop on nano-biosensors said that their development and prototype production was a very difficult "value proposition" for private investors.[iv] Since one challenge of developing exposure data is to do so in a non-invasive way that will not create data "artifacts" leading to false inferences, Department and Agency investment in funding or co-funding nano-biosensors should accelerate the development of exposure data from nanotechnology-enabled products in real media, e.g. soil, rather than purified laboratory sand.

Can the challenge be achieved in the next decade? If not, how long will it take?

Several of the QEEN presenters said that the first ten to twelve years of research since the founding of the NNI had largely been devoted to characterizing the properties of "pristine" or "native" ENMs in highly controlled laboratory settings. As difficult as that research was, designing experiments and instrumentation to quantify the release of ENMs in products during different phases of their life cycle in the media of their use will be yet more difficult. However, if the liability prevention experts who have advised the nanotechnology industry not to submit ENMs to the Environmental Protection Agency's voluntary ENM stewardship program continue to prevail, the project to organize a comprehensive exposure database to enable high through-put toxicological assessments of ENMs in their product matrix during their life cycle will be delayed, perhaps beyond a decade. The OSTP and the NNI will need a legal strategy to negotiate with the

nanotechnology industry's legal counsel to expedite both the submission of nanotechnology-enabled products and ENMs used in specific products and the industry's assistance in developing exposure databases and predictive toxicological profiles for present and future ENM compounds. The OSTP must not allow dogma, according to which regulation and regulatory science stifle innovation, to undermine the development of nanotechnology products and ENMs safely developed, produced and used.

IATP wishes to thanks OSTP again for the opportunity to submit these brief comments, and would be pleased to respond to any feedback that you may have about them.

Respectfully submitted,
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[i] https://www.federalregister.gov/articles/2015/06/17/2015-14914/nanotechnology-inspired-grand-challenges-for-the-next-decade

[ii] http://www.iatp.org/blog/201507/no-small-task-generating-robust-nano-data

[iii] https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf

[iv] http://nano.gov/sites/default/files/pub_resource/nnisensorsworkshopreport.pdf