

Draft 2014 National Nanotechnology Initiative (NNI) Strategic Plan

Friends of the Earth US and Australia Submission



Friends of the Earth US and Australia deem the NNI Strategic Plan inadequate on the basis that the plan fails to meaningfully address the environmental, health and safety (EHS) aspects of nanotechnologies. The flaws of the NNI Strategic Plan include:

1. Support for commercial applications and promotion of nanotechnology dominate the NNI Strategic Plan despite many doubts and concerns from experts internationally with regard to the safety and efficacy of engineered nanomaterials (ENMs).
2. EHS matters are not a priority for the NNI and this is apparent in almost every aspect of the Strategic Plan:
 - a) Existing human and environmental health concerns from ENMs are barely acknowledged;
 - b) Potential serious concerns surrounding the release of ENMs are not given any priority in the EHS component of the Strategic Plan;
There is no apparent strategy for assessing EHS concerns for existing and commercially available ENMs;
 - c) The need for regulation is virtually invisible from the Strategic Plan. In order for EHS concerns to be effectively addressed, regulatory options must be part of the NNI's considerations;
 - d) No mention is made of the lack of labeling and a registration system that would assist in EHS assessments;
3. As with EHS, "foundational research" (see p. 41) is given little priority though critical to EHS assessments.
4. Ethical, legal and social implications (ELSI) of nanotechnology are given no priority

1. Commercial bias in the Plan

The bias in the NNI Strategic Plan is apparent throughout the document. For example, the Vision and Goals (p. 3) section includes no mention of EHS. The section does mention public good, however, this would benefit from a proper definition, as the current implied definition is that if something is good for business then it is automatically good for the public.

The NNI Strategic Plan wishes for commercial development to continue 'unabated' (p. 11) meaning that the current release of ENMs into the environment and our bodies will endure with little or no understanding of risks in doing so.

The support for "unabated" commercialization and the need to "maximize return on the Nation's research investments" (p. 44) clearly indicate that commercial interests are the primary priority for the NNI.

2. EHS matters are not a priority for the NNI

EHS appears to be a peripheral issue for the NNI. The lack of priority given to EHS is of great concern. Despite the existence of a now very large body of peer reviewed work raising concerns about various ENMs and their potential impacts on human health and the environment, not a single specific concern is raised in relation to existing ENMs and uses. While the Strategic Plan generally recognizes that risks must be assessed, it is difficult to understand how EHS will fit in with the NNI's goal of rapid commercialization of nano products. There is no recognition that ENMs already in the environment or used in food or medicines represent particular risks or create specific priorities in terms of assessment or the development of tools to identify, monitor or remove ENMs. There is no discussion of the role EHS research plays in the development and pre-release work done on ENMs and there is no discussion of how EHS research is going to catch up to the plethora of ENMs already released.

The EHS strategy appears woefully disconnected from the applications that it should be assessing (and regulating) before release. The NNI Strategic Plan does not seem to recognize the work of the National Research Council (NRC), which has systematically considered EHS efforts that need to be enacted (2013 *Research Progress on EHS Aspects of Engineered Nanomaterials*).

Thousands of nano products are now on the market, but as the NRC has pointed out we still lack basic elements for assessing EHS, including tools and instruments that will allow consistent and reliable tests and analyses. This includes developing standardized assays (NRC p. 53); developing reference materials (NRC p. 53); calibrating and validating models (NRC p. 54); and developing inventories of nanomaterials and definitions (NRC p. 57). The EHS component of the NNI Strategic Plan must address existing uses, identify levels of risk, develop priorities for assessment based on current science and identify research needs in order to ensure the safety of new ENMs before they are released into the environment.

It should be a fundamental principle of the NNI Strategic Plan to ensure that new ENMs are not released unless and until it is established that they are safe for humans and the environment. This Strategic Plan assumes that a kind of contemporaneous process can occur – unabated commercial development and an EHS program that is unrelated. In light of the mounting evidence of serious health and environmental concerns with a number of ENMs, this is a profoundly reckless approach. Inevitably there will be harmful impacts. The costs associated with such impacts will be borne by the public, costs which will be much higher than if addressed proactively.

Section 4.2 (Goals and Objectives) and subsections deal with EHS goals. The overarching goal (4.2) is to “Create and employ means for timely dissemination, evaluation and incorporation of relevant EHS knowledge and best practices.” There is no mention of precaution, protection, prevention or remediation. Subsequent sub-goals (4.2.1 – 4.2.3) suggest that EHS research is intended to serve as advice to those engaged in commercialization. The use of words such as “explore” and “promote” indicate that there is little weight given to EHS concerns and that commercial applications remain the highest priority.

The 2013 NRC review of NNI progress in achieving the EHS priorities that the NRC had identified in 2012 concluded that of the 20 indicators of progress identified in 2012, little or no progress had been made on 19 indicators (pp. 6-7). It is deeply concerning that the NNI strategy neither mentions the initial NRC paper, its review, or the cogent arguments for greater investment in EHS research.

In both areas of health and environment, the NRC found that necessary and even critical research is not keeping up with commercialization. The health related research that is not progressing adequately includes identifying:

- human populations that are exposed to ENMs and the magnitude of exposure(s) (NRC p. 59);
- toxicity mechanisms and pathways of ENMs examined under realistic conditions (NRC p. 65);
- reliable models that can accurately predict nanomaterial releases and likely human exposure (NRC p. 61);
- critical release points along the supply chain (NRC p. 59).

In terms of environmental assessment, there is little information regarding:

- impacts on ecologically relevant species;
- ecosystem-level effects associated with chronic low-dose exposure to ENMs (NRC pp. 54, 66);
- magnitude and types of exposure in different ecosystems, such as water, aquifers, air, soil, food, waste and wastewater (NRC p. 59);
- How alterations in the chemistry of ENMs may affect ecosystem exposure (NRC pp. 59, 62);
- the life cycles of different ENMs (NRC p. 59);

Many of the issues raised by the NRC relate to basic levels of research that are needed in order to assess the safety of any release of ENMs. It is extraordinary that the NNI lacks consideration of serious governance and science failures while unabated commercialization of nanotechnologies persists in the context of such

profound knowledge gaps.

One of the major issues raised by the NRC report is that the NNI has a dual role in both promoting and assessing nanotechnology. It appears that NNI is so locked into its promotional role that it is not capable of fulfilling the EHS research needs associated with nanotechnology. This is a situation that clearly needs to change.

Regulatory Needs

4.4.1 - "Encourage the use of ENMs that are safer and more sustainable alternatives to currently used materials." While this section does – unusually for the Strategic Plan – recognize the potential risks of current ENMs, it is clear (again) that EHS matters will be 'incorporated' through encouragement and the kinds of voluntary measures that have historically failed. While the NNI involves numerous regulatory bodies, regulation is virtually ignored in the entire Strategic Plan. If one looks at the current state of EHS research and foundational knowledge, it is clear that regulatory intervention is needed at a number of points, from R&D stages, to pre-release, release, monitoring, enforcement and remediation. There is clearly neither intent nor interest in setting up the regulatory structures and frameworks that this new technology will require.

3. Foundational Research

The foundational research identified in the NNI Strategic Plan is crucial and should be a first priority; including the establishment of agreed definitions, nomenclature, testing methodologies, reference materials, etc.

In relation to foundational knowledge, the NRC concluded that for purposes of EHS research we are lacking:

- well characterized nanomaterials both to understand how structure influences effects (NRC p. 52) and to identify potential hazards (NRC p. 67);
- standardization in organisms and experimental conditions (NRC p. 53);
- standardized reference materials and reference materials to use as controls (NRC p. 53);
- inventories that describe what ENMs are being produced and how they are being used (NRC p. 57).

4. Research into the ethical, legal and social implications (ELSI) of nanotechnology is given no priority

4.3 – "Develop the national capacity to identify, define and responsibly address concepts and challenges specific to the ethical, societal and legal implications (ELSI) of nanotechnology." We must acknowledge that this goal is articulated by the NNI in the context of 'unabated' commercialization of ENMs, therefore lacking ambition, which will create a void of findings that influence the commercial imperatives, applications or outcomes (these already far outstrip any consideration of ELSI) and will not be part of any meaningful or participatory public process.

Conclusion

It is critical that the NNI move away from an extreme free market approach to the commercialization of nanotechnologies – i.e. to "maximize return on the Nation's research investments." As a first priority, the NNI must recognize that failure to develop foundational knowledge and undertake thorough pre-release assessment of ENMs will result in the public having to inevitably pay the price for untested, unmonitored and poorly understood ENM release. Those costs will not be purely monetary and may occur at a scale that makes them irreversible.

The expectation from NNI that interested parties would be able to limit comments to less than one page in response to a 79 page document was unreasonable. We trust our additional pages of comments will be considered and documented.