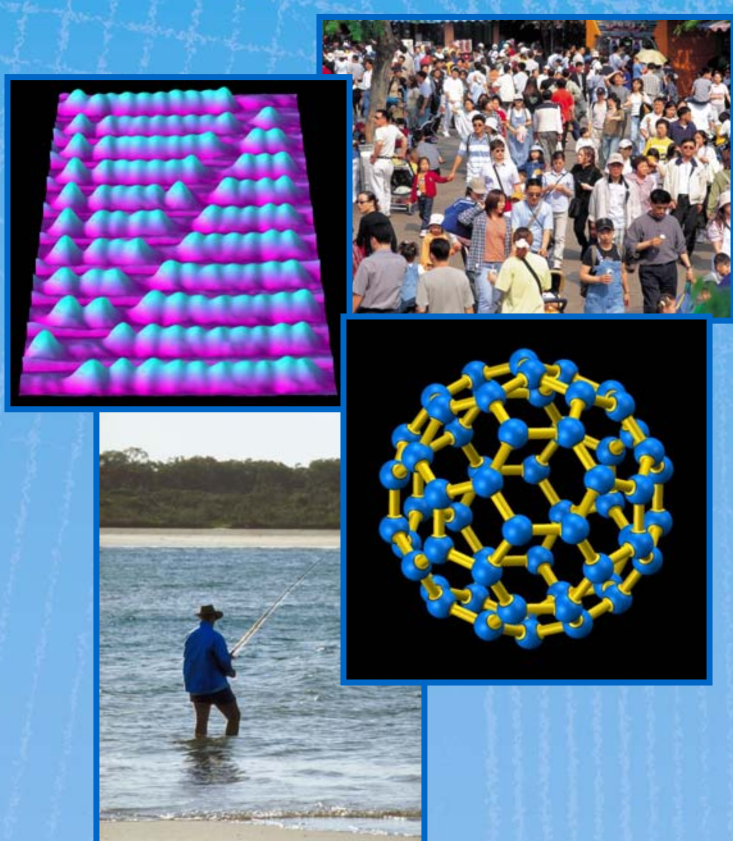
Characterizing the Environmental, Health, and Safety Implications of Nanotechnology:

Where Should the Federal Government Go From Here?

December 2006



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Feedback

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Summary

The United States needs to chart a more aggressive course when it comes to understanding the environmental, health, and safety (EHS) implications of nanotechnology. Valuable work has already been done in this arena, but much more research is necessary, especially given the rate at which nanotechnology is evolving.

ICF's analysis of the national effort to characterize the EHS implications of nanotechnology is intended to yield actionable insights. By reviewing the current state of research and analyzing approaches to accelerating high-priority research, we have developed a strategic research framework that can set the stage for a more comprehensive research plan. Our key recommendations are summarized below. A more thorough explanation of the rationale for each recommendation is contained in subsequent sections of this paper.

1: Funding for Federal EHS research should be increased substantially, and the portfolio of research should be managed in a more proactive, systematic, and strategic manner.

2: Overarching management of the national research effort is just as important as the underlying scientific work. Effective business processes operating within a sound strategic framework are the only way to ensure a successful program.

3: Federal policymakers should explicitly address the following four objectives in an integrated fashion. Program success requires a definitive "yes" to each of these questions:

- Identifying the "Right" Research: Does the research inform priority risk management decisions?
- Managing the Research Effectively: Is research completed in a timely, policy-relevant, and cost-effective manner?
- Applying Research Effectively: Is the research disseminated broadly and used to enhance the quality of risk management decisions?
- Ensuring Continuous Improvement: Is ongoing feedback about the quality and utility of the research used to enhance a sustained nanotechnology EHS research function?

4: The risk research agenda should be developed primarily by reverse engineering the priority risk management decisions. This means first identifying the risk assessment needs associated with those decisions and then working backward to determine what risk research is required to conduct such risk assessments, including methods and nomenclature development.

5: Federal regulators responsible for risk management decisions must have a substantial say in creating a more comprehensive research agenda. To give a voice to "orphan" risk issues not taken up by Federal regulators, Federal researchers and nongovernmental stakeholders should be heavily involved in efforts to prioritize the risks.

6: New EHS research programs must reflect a mix of strategic "top-down" national priorities set through interagency collaboration and more opportunistic "bottom-up" research priorities put forward by individual regulatory and research agencies and non-Federal stakeholders. "Bottom-up" research must be centrally reviewed and coordinated.

7: All new EHS research programs should be reviewed by a multiagency Federal Nanotechnology EHS Research Council prior to initiation. Agencies could move forward with research the council had declined to endorse but would have to publicly provide a detailed rationale for doing so. The council should not rely on consensus-based decision making but instead follow a voting system where each agency has one vote.

8: Council deliberations should be informed by an independent scientific assessment that biennially reviews policymakers' information needs, the state of the literature, and gaps between the two. The National Research Council, for example, could lead such reviews.

9: Research sponsors must recognize that EHS research is often "applied research," while most Federal investments to date in nanotechnology are in "basic research." Management of Federally funded EHS research must reflect this difference.

10: Specific EHS research questions should be developed proactively by research sponsors based on policymakers' information needs rather than primarily in reaction to researchers' proposals. Sponsors should issue more narrowly focused solicitations; doing so may entail greater use of research contracts and cooperative agreements to ensure that the research is as proactively managed and policy-relevant as possible.

11: All potential researchers — academia, contractors, industry, and other Federal agencies — should be allowed to participate in research. This will allow the research solicitor to distribute resources most efficiently to answer specific research questions.

12: An effective knowledge management system for EHS research is a prerequisite for success. It must provide a comprehensive bridge between the sources of information and the users of that information. The knowledge management system should be seen as a hub, proactively pulling information from researchers and other sources, compiling and organizing the information in a coherent fashion, and pushing it out to those who need it.

13: To accommodate a fast-evolving field, the national EHS research effort should be flexible and adaptable. Supported research should be demonstrably relevant to important risk management decisions, applicable to those nanomaterials likely to move through the development pipeline toward commercialization, and tightly linked to other research.

14: To ensure continuous improvement, the national EHS research program should be subject to ongoing review — both internally and externally. It also seems prudent to build in a "sunset" provision. After perhaps ten years, the authority and funding for research efforts might automatically lapse. That's not to say that all research would be finished in 2016 and that the Federal role would end; rather, the sunset provision is a mechanism for ensuring that a debate takes place about the appropriate approach on a go-forward basis.

In addition, we offer a final suggestion:

> ***Significant progress in the coming months requires prompt initiation and management of building a plan for a larger and better-integrated EHS research program. This is not the same as launching the revamped research program itself; instead, the need is for a roadmap that gets the community to the point where such a program can be launched.***

The intent of this document is to make a meaningful contribution to the development of such a roadmap. With map in hand, the specific path forward will be much clearer. Moving down that path will facilitate the creation of a policy infrastructure that maximizes the benefits of nanotechnology while simultaneously protecting human health and the environment.

1. Framing the Issue

Nanotechnology is driving a technological transformation akin to the computing revolution of the late 20th century. It is expected to generate profound innovations in the fields of medicine, energy, information technology, transportation, environmental protection, and consumer products. With the promise of nanotechnology, however, comes uncertainty. Because it allows creation of materials with unique and novel properties, questions arise about its implications for the environment and for the health and safety of workers, consumers, and communities.

- How do different nanomaterials behave if released into the environment?
- What are the health and safety risks in consumer goods or in an occupational setting?
- What are the ecological consequences of releases to the environment?
- How can potential risks be effectively mitigated?

With unanswered questions like these, there is a need to increase our understanding of the environmental, health, and safety (EHS) implications of nanomaterials before the technology is fully realized as the trillion-dollar industry that it will become.[1]

ICF International prepared this white paper to help frame the key issues, describe options for addressing those issues, and make recommendations about potential next steps. The path forward will be the product of robust debate; this paper contributes to the debate by offering actionable insights to help the United States maintain its advantage in the promising new field of nanotechnology. The remainder of this first section frames the issue.

EHS Research Is Integral to the National Effort to Develop Nanotechnology

As a starting point, available evidence suggests that the creation and use of nanomaterials pose a potential risk to human health and the environment. By potential risk, we mean a reasonable possibility of significant adverse consequences from the unfettered development and application of nanotechnology. We do not suggest that adverse consequences are a certainty or that they outweigh the potential benefits of nanotechnology or that they cannot be mitigated satisfactorily. These risks, however, merit careful consideration. As indicated in Exhibit 1, several others subscribe to this point of view.

In addition, perceptions of risk — not based on scientific evidence — may develop in the absence of definitive research and manifest themselves in a public backlash against nanotechnology. Substantial disagreement exists, but many observers point to the example of limited development of genetically modified organisms (GMOs) and identify perceived risk not based in scientific assessment as the driver of strict European regulation of GMOs.

In the absence of Federal intervention, several factors may combine to impede EHS research on nanotechnology. Although many manufacturers investigate EHS issues and develop safe management practices, industry often focuses more on product development than EHS risks when developing technologies with minimal regulatory guidance. Some firms may lack the resources or expertise to fully investigate EHS issues. In addition, addressing these issues in an academic setting may be hindered by the need to work across departmental lines (e.g., among materials science, public health, and ecology).

Exhibit 1: EHS Risks From Nanotechnology Warrant Careful Consideration

Commenter	Conclusion
John Marburger, III Science Advisor to the President and Director of the Office of Science and Technology Policy	"The novelty of nanoscale materials arises from the fact that with decreasing size, the properties of materials change. Such changes, however, may be accompanied in some cases by increased environmental, health, and safety risks."[2]
National Research Council Committee to Review the National Nanotechnology Initiative, National Materials Advisory Board	"[Nanomaterials] can have unknown and possibly negative impacts, such as unexpected toxicological and environmental effects. … EHS research published to date has provided some data indicating the potential for risks to laboratory animals exposed to nanomaterials and has shown that much more work is needed to assess the potential risks involved."[3]
Andrew Maynard, et al Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars	"Fears over the possible dangers of some nanotechnologies may be exaggerated, but they are not necessarily unfounded. … It is generally accepted that, in principle, some nanomaterials have the potential to cause harm to people and the environment."[4]

Exhibit 2 explains how impediments to comprehensive EHS research can have significant consequences. In this circumstance — and consistent with the general environmental policy framework in the United States — it becomes the government's responsibility to ensure that EHS risks are characterized and that prudent steps are taken to protect human health and the environment. Because nanotechnologies are being commercialized in all states, the Federal government is the appropriate level of government to lead this effort. As explained below, it already has begun to do so.

Exhibit 2: EHS Research Can Prevent Potential "Policy Mistakes"

Statisticians distinguish two types of mistakes that can happen when reaching conclusions using uncertain information. Known as Type 1 and Type 2 errors, they occur when a hypothesis is assumed to be false when it is true or, conversely, when a hypothesis is thought to be true when it is false. There is an analogy to nanotechnology policy:

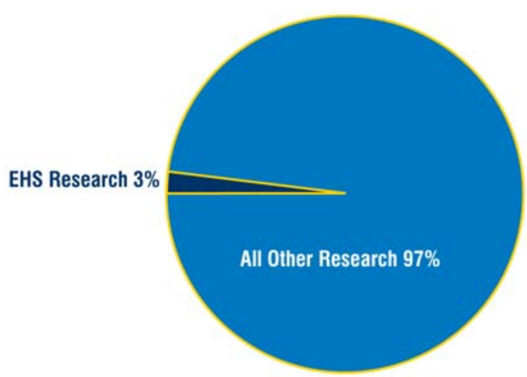
- Policymakers could assume nanotechnology is essentially safe and allow widespread commercialization, only to later discover significant health or environmental effects, akin to those of asbestos, lead, and CFCs.
- Policymakers could assume nanotechnology is very risky and prohibit most uses, foregoing the benefits of the new technology and undermining national competitiveness, only to later find that the concerns were unfounded.

Both types of policy mistake could have significant social and economic consequences. What's more, a well-designed and implemented EHS research strategy can go a long way toward minimizing the chance of either type of policy mistake.

Funding for Federal EHS Research in Nanotechnology Should Increase Substantially

The Nanotechnology Environmental and Health Implication (NEHI) Working Group reports that several dozen research programs are being conducted by 16 Federal agencies that participate in NEHI.[5] In 2006, spending for such activities is projected to top $37 million. By comparison, total spending on nanotechnology research across the Federal government is $1.3 billion annually. As shown in Exhibit 3, EHS spending comprises 3% of the total.[6]

Exhibit 3: FY 2006 EHS Spending Is a Small Fraction of Federal Nanotechnology Research Spending



How much *should* be spent on EHS research? One "top-down" answer was provided in an op-ed published in *The Wall Street Journal* in which the CEO of DuPont and the president of Environmental Defense (ED) argued that "government spending on nanotechnology should be reprioritized so that approximately 10% goes to [studying health and environmental risk]."[7] Given total funding of $1.3 billion, the DuPont-ED position implies funding of more than $100 million per year. The Wilson Center's Project on Emerging Nanotechnologies used a "bottom-up" approach to estimate spending needs of $106 million to achieve 36 specific research goals at four Federal agencies over a two-year period.[8]

Although it did not endorse a specific budget target, a group of major industry representatives (including BASF, Bayer, Degussa, DuPont, and PPG) and nongovernmental organizations (Environmental Defense, Union of Concerned Scientists, Natural Resources Defense Council, and the NanoBusiness Alliance) recently called on the U.S. Congress to "significantly increase appropriations directed to research on the health and environmental implications of nanotechnology."[9] Put simply, members of Congress representing both parties, as well as environmental groups, industry groups, companies large and small, think tanks, and academics, all have argued that Federal funding for EHS research should be substantially increased.

Management of the Federal EHS Effort Can Be Improved Significantly

In addition to funding levels, management of the Federal EHS effort also has come under scrutiny. Though not disputing the value or quality of current EHS research, critics of the Federal nanotechnology EHS research program find fault with the lack of a strategic framework to guide the entire research program. Exhibit 4 presents a representative sample of such criticism.

Exhibit 4: Management of Federal EHS Research Efforts Can Be Improved

Commenter	Conclusion
Sherwood Boehlert Chairman, Committee on Science U.S. House of Representatives	"[The NEHI report] on research needs … [is] only a first step, and it doesn't fully set priorities, never mind assign them. So we're on the right path to dealing with the problem, but we're sauntering down it when a sense of urgency is needed."[10]
Matthew M. Nordan President and Director of Research Lux Research, Incorporated	"Nanotechnology EHS research in government agencies, academic institutions, and industrial facilities is expanding, but it is being performed in an ad hoc fashion according to individual priorities that … risk costly duplication of effort and raise the specter of key issues remaining unaddressed. … This is not surprising because NEHI has no authority to mandate such priorities and cannot allocate funding."[11]
Andrew Maynard Project on Emerging Nanotechnologies Woodrow Wilson International Center for Scholars	"There are clear gaps in the [EHS] research portfolio. ... I am more concerned over the lack of an apparent top-down strategy that couples risk research to real information needs. … Implicit in a strategy is the setting of hard priorities, the linking of those priorities to actual multiyear funding levels, and the development of metrics to measure results over time. There is a large difference between a strategy and a list of research needs."[12]

Because the capabilities required for execution of a risk research strategy are spread across Federal agencies, an interagency collaboration is required. Although the NEHI working group engages Federal researchers in discussion of EHS research needs and the National Nanotechnology Initiative (NNI) convenes coordinating meetings and catalogs Federal research, neither is empowered to set research budgets, fix priorities, or direct agencies to pursue specific research projects. Instead, research at each of the 16 participating agencies is often conducted under its own agenda. Typically, staff from each agency does the following:

- Reports to different leadership
- Serves unique stakeholders
- Operates under separate budgets
- Answers to different congressional committees
- Has different capabilities and resources
- Implements different statutes and missions

Not surprisingly, interagency collaboration is difficult. No matter how collaborative the participants or the degree to which there is a shared sense of mission, interagency collaboration can be cumbersome to manage without clear lines of authority and decision-making processes.

What's more, improving management of the Federal EHS research effort is an urgent matter. Nanotechnology is evolving rapidly, and many products are already in the marketplace. Research projects often extend over a multiyear period, and cumulative research built on prior results is sometimes needed to answer key questions. Andrew Maynard, former cochair of the NEHI Working Group, writing in the November 2006 issue of the journal *Nature*, argues that strategic programs that enable relevant risk-focused research must be developed "within the next 12 months."[13]

2. The Challenge Is Not Just About Science, It's Also About Management

A successful research program that keeps pace with the rapidly evolving field of nanotechnology requires more than a roster of research projects; it demands a strategic framework and an effective management plan. Previous reports by NNI, the National Institute of Occupational Safety and Health (NIOSH), and others have identified research needs and offered suggestions for research management. What is missing is a comprehensive, government-wide strategy for EHS research and a detailed operational plan, as well as a decision-making process for setting priorities and executing the program.

The management challenge of EHS research is distinct from the scientific challenge. Both are vital, but addressing one without addressing the other is not sufficient and could be counterproductive. As shown in Exhibit 5, policymakers must execute a research strategy that *identifies, manages,* and *applies* research in an effective manner. The strategy also must be sufficiently *adaptable* so that it can keep pace with the rapid evolution of nanotechnology over the next several years. Each element of the strategy should be built around a core objective and a foundational question. Program success requires a definitive "yes" to the following questions.

(1) **Identifying the "Right" Research**: Does the research inform priority risk management decisions?

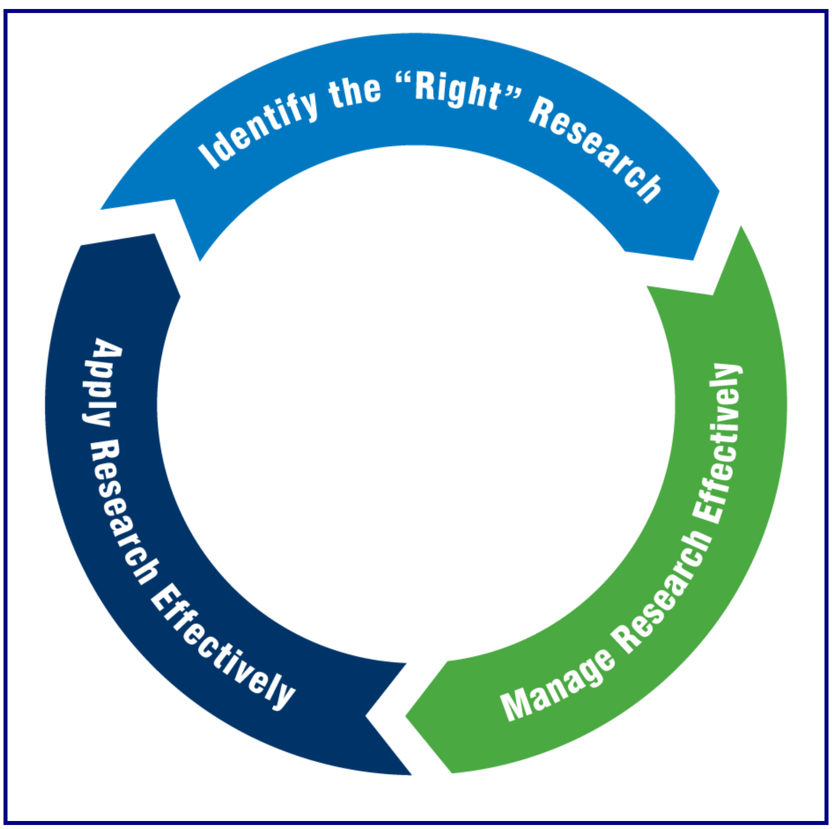
(2) **Managing the Research Effectively**: Is research completed in a timely, policy-relevant, and cost-effective manner?

(3) **Applying Research Effectively**: Is the research disseminated broadly and used to enhance the quality of risk management decisions?

(4) **Ensuring Continuous Improvement**: Is ongoing feedback about the quality and utility of the research used to enhance a sustained nanotechnology EHS research function?

Remaining sections of this white paper explore each management objective in more detail, offering both broad strategic principles as well as tactical options for achieving each objective.

Exhibit 5: EHS Research Must Be Managed Holistically



3. Identifying the "Right" Research: Does It Inform Priority Risk Management Decisions?

The NEHI Working Group's September 2006 report, "Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials," cataloged a range of EHS research needs related to nanotechnology. Its table of contents lists more than a dozen areas of broad research interest; within each are several specific risk questions and potential areas for investigation. Sorting through these research issues to identify priorities is a daunting task. In fact, the NEHI report stops short of doing so, saying that "further prioritiz[ing] research needs" is a "next step."[14] As described in Section 3.1 below, ICF has identified three design principles that will make the challenge of identifying and prioritizing the "right" research easier. Section 3.2 then lays out some specific approaches that could be used to operationalize these principles.

3.1 Design Principles

The research agenda can be set by reverse engineering the risk management process.

Risk research provides information for defensible and credible risk assessments which, in turn, are the foundation of sound risk management decisions. Research is valuable only to the extent that it informs risk management decisions and is *most* valuable when it informs risk management decisions in areas of greatest EHS concern. As shown in Exhibit 6, even though research is the first input in risk management, setting a research agenda is a matter of "reverse engineering," or working backward from the necessary outcomes to the required data inputs.

Consider the example of nanomaterials in cosmetic products and a policymaker who needs to make a risk management decision by, for sake of illustration, choosing among the following options:

- Continuing current formulations of nanomaterials in cosmetics
- Eliminating or reducing the concentration of nanomaterials in cosmetics
- Continuing current formulations but issuing additional usage guidelines

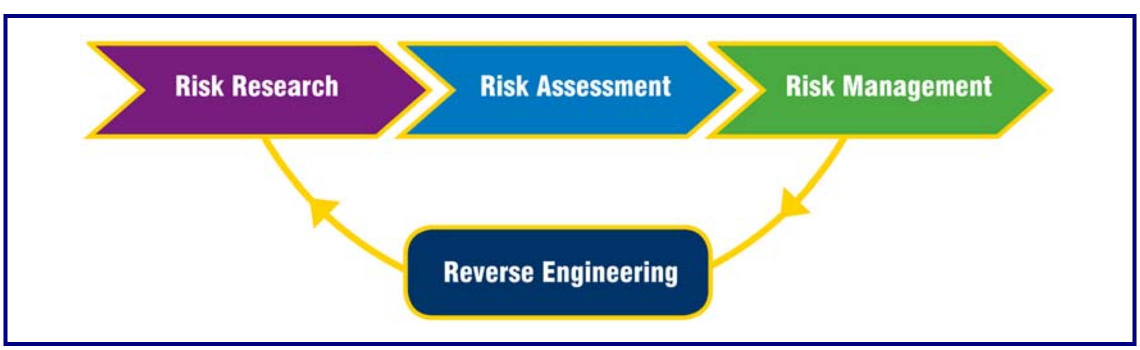
Given the identification of cosmetics as a priority and having defined three possible choices for risk management, one can work backward to identify (i.e., reverse engineer) the risk assessments needed to support risk management decisions. Simplifying significantly, we can say that a risk assessor must do the following:

- Identify Hazards by characterizing nanomaterials of concern within the cosmetic product
- Assess Exposure by characterizing consumer behavior with regard to application to the skin, such as frequency of application and body locations to which the cosmetic is applied
- Assess Dose-Response by evaluating rates of dermal uptake of nanomaterials and the corresponding health impacts
- Characterize Risk by applying toxicity information to predict health effects

Continuing our simplified illustration, conducting a risk assessment of nanomaterials in cosmetics might then require information about the following factors:

- Product formulations and consumer use of the product
- The relationship of dermal exposure to quantities of nanomaterials taken up by the body
- Behavior of nanomaterials in the body
- The consequences of those nanomaterials for the body's systems and their functioning

Exhibit 6: Research Management Requirements Should Drive the Research Agenda



These information needs form the core of a research agenda. Finally, we can ask whether all of the requisite nomenclature, test methods, assays, sampling and laboratory equipment and methods, and other relevant standards exist. If not, such needs can be added to the agenda.

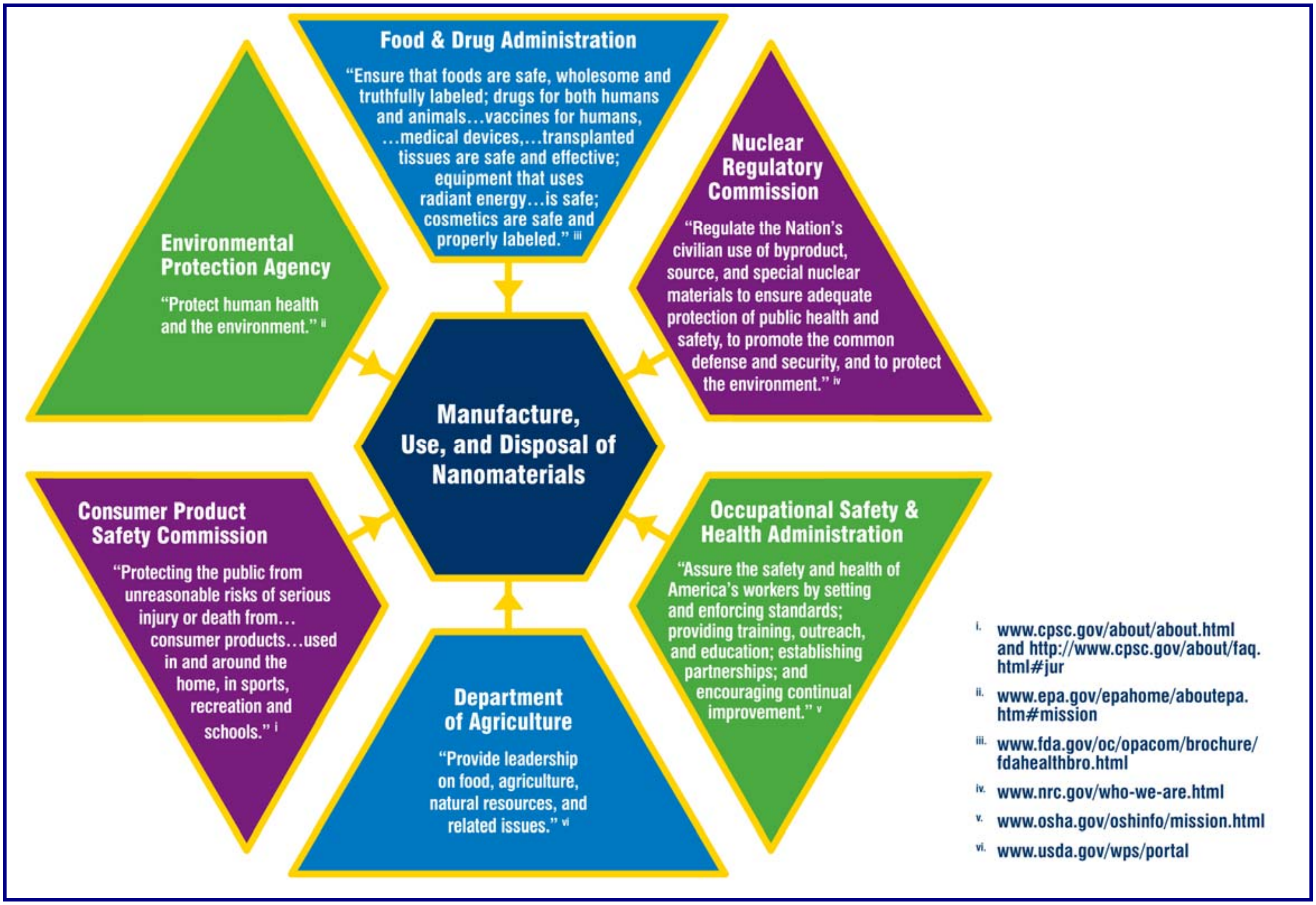
Because the reverse engineering principle starts with priority risk management decisions (e.g., in the example from above, management of nanomaterials in cosmetics), the question arises as to how to determine which risk management decisions merit the highest priority. To fill this gap, two additional principles must be considered.

Risk managers ought to have a substantial say in developing the risk research agenda.

Several Federal agencies have as their mission protecting some aspect of human health or the environment. Exhibit 7 lists the agencies identified by NNI as having regulatory oversight of nanotechnology as part of their core missions.[15] These agencies collectively have responsibility for virtually all aspects of the manufacture, use, and disposal of products containing nanomaterials.

It is their regulatory oversight functions — their responsibility for risk management decisions — that give these six agencies important roles to play in setting the agenda for EHS research related to nanotechnology. Because of the reverse engineering principle described above, it is vital that the regulatory agencies help frame the research agenda. Not only do these agencies have deep knowledge of the industries they regulate, but they also have an intimate understanding of their statutory authorities and risk management paradigms.

Exhibit 7: The Collective Mission of Federal Regulators Addresses Virtually Every Aspect of Nanotechnology



Responsible for the risk management decisions under their jurisdictions, regulators also are "consumers" of research results with an interest in seeing that "suppliers" provide information that is directly relevant and applicable to risk management decisions. Accordingly, institutional arrangements must give regulators a prominent and ongoing role in directing the research agenda.

Several factors may, however, impede the ability of regulators to fully identify and prioritize all of the relevant risk management decisions related to their missions.

- Some agencies face severe budget and staffing constraints under which they struggle to address their existing workload, let alone new challenges associated with oversight of nanotechnology. J. Clarence Davis, for example, questions the Occupational Safety and Health Administration's ability in this regard, saying that the agency "traditionally has been starved for resources."[16]
- In other cases, a regulatory agency may operate under statutory authorities that limit its focus in important areas. The Food and Drug Administration, for example, has limited authority over cosmetics, a product area where nanomaterials are already being used.
- Finally, most agencies' existing regulatory frameworks were built prior to the emergence of nanotechnology and thus have gaps through which nanomaterials may fall. Environmental Protection Agency (EPA) regulations, for example, exempt from premanufacture notice requirements under the Toxic Substances Control Act those substances manufactured in quantities of 10,000 kilograms or less per year[17] — a threshold that may not be meaningful in the context of nanotechnology where surface area or particle diameter may be more important.

While regulators must play a leadership role in creating the research agenda, impediments like budget constraints, statutory limitations, and dated regulations mean that they cannot identify all of the risk management issues associated with nanotechnology. In turn, conducting EHS research to support only the risk management decisions that regulators *can* or *will make* leaves a gap in the research agenda. This gap leads to what ICF calls "orphan" risk management issues, which regulatory agencies are unlikely to address in the near term.

A mechanism must ensure that orphan risk issues are placed on the research agenda.

When it comes to orphan risk issues — those not being addressed by regulatory agencies for some reason — we need to look to other stakeholders for input. Some are part of the Federal government, and others are not.

Some Federal agencies don't have a policymaking or regulatory mission but support agencies that do. NIOSH is responsible for research and advice on issues related to workplace health and safety risks. NIOSH has a substantial program in nanotechnology risk research that operates under a broad strategic framework published in draft form in 2005.[18] Similarly, the Nanotechnology Safety Initiative (NSI), under the auspices of the National Toxicology Program (NTP), operates a broad research program directed at the potential human health hazards of nanomaterials during manufacture and use.[19] The National Institute of Environmental Health Sciences (NIEHS) plays a leadership role in NTP, but NIOSH and a research center at FDA are also active participants.

NIOSH and NIEHS are examples of Federal stakeholders without a direct regulatory mission who offer deep expertise, relevant experience, and current involvement in EHS issues. It is imperative that they help prioritize the national research agenda. As Federal officials, they serve a broad public interest rather than the potentially narrower interests of nongovernmental organizations.

Another way to ensure that orphan risk issues do not get left off the risk research agenda is to include nongovernmental stakeholders in the process. For example, a congressionally chartered but private organization — the National Academies — can offer an independent and highly credible source of scientific information. By way of example, Congress asked the Board on Environmental Studies and Toxicology (BEST) at the National Research Council (NRC) to review research to support EPA's airborne particulate matter program from 1998 to 2002. Congress charged the NRC with assessing research priorities, developing a conceptual research plan, and monitoring progress. Through the establishment of an independent committee composed of air quality experts, NRC published four reports on research priorities, which both prioritized and identified research topics linked to key policy-related scientific uncertainties and evaluated the progress of the research program.[20]

Companies developing nanotechnologies also have substantial expertise in the materials they are developing and commercializing. In addition, interest groups — representing both industry and environmental concerns — bring vital perspectives and expertise to risk research issues. Finally, the academic community working in the field of nanotechnology understands the current state of the science and can identify logical next steps for further research.

Involvement of a broad array of stakeholders — both Federal and non-Federal — working outside the regulatory process will minimize the chance that the inevitable constraints on Federal regulators — budgetary, statutory, and the like — inappropriately limit EHS research efforts. This involvement, however, must be carefully coordinated and integrated under a strategic research planning and implementation process.

3.2 Design Options

Although the September 2006 NEHI report catalogs the activities of multiple Federal agencies and describes successful collaborations among agencies, it says little about the governance and oversight of the Federal government-wide EHS research effort. Two witnesses at the September House Science Committee Hearing suggested that centralized control of the Federal EHS research effort is needed. Andrew Maynard argued that "a new interagency oversight group should be established with authority to set, implement, and review a strategic risk research framework,"[21] while Matthew Nordan testified that "a new, interagency body" with "authority to mandate priorities" and "allocate funding" is required.[22]

We concur that an interagency group should lead the Federal EHS research effort to optimize its relevance, quality, and efficiency. Ideally, the group should be housed in an existing agency with a relevant mission. Otherwise, the setup of a new organization could be time-consuming and may entail a steep learning curve.

In addition to finding an organizational home for this interagency group, the design features of the group's governance and operations must be specified. Below we offer some suggestions premised on the assumption that, as noted in Section 1, Federal funding for nanotechnology EHS research will be increased substantially by several tens of millions of dollars per year.

Mindful of the urgency with which EHS research must be pursued, we aimed to be as pragmatic as possible. We sought solutions that would not require new authorizing legislation from Congress nor the establishment of new agencies. Instead, the recommendations described below could be implemented through the appropriations process, with appropriations legislation or the accompanying committee report language making clear the congressional intent.

We also recommend that existing research programs generally be left untouched. Dozens of research efforts are underway at several agencies. These efforts will yield important insights and also represent valuable momentum. Hence, the eight suggestions offered below apply to incremental funding that would be made available. Building these features into the design of the interagency group will enhance its prospects for success.

1. **Funding**: The incremental funding for Federal EHS research should not be appropriated to a single agency; doing so might spark a lengthy debate about which agency should get the funding. Instead, funding should be spread among the agencies materially involved in the EHS component of the NNI in rough proportion to their current spending for EHS research. Such resources would be made available by an offsetting, "across-the-board" reduction in other Federal nanotechnology spending. Although doing so may not prevent debate over funding, maintaining the proportionate redistribution of resources may facilitate prompt action on funding, although it would involve multiple appropriations subcommittees and thus require additional coordination. Nonetheless, interagency collaboration on specific research programs would be encouraged. Over time as research priorities become clearer, EHS research funding should be allocated to reflect the workload taken on by each agency.
2. **Research Program Review**: Even though funding for EHS research would be provided to agencies by direct appropriation, the agencies would be required to submit proposed research programs for review by a Federal Nanotechnology EHS Research Council before obligating the funding. The council would provide one of three responses by (1) endorsing, (2) recommending changes to, or (3) declining to endorse each proposed research program. Agencies would not be obligated to adhere to council recommendations but would have to make public its detailed rationale for moving forward with any program the council declined to endorse. After council approval, agencies would be responsible for administering extramural funding in the form of grants, contracts, or cooperative agreements.
3. **Decision Making**: While operating in a collegial fashion, the council would not make decisions by consensus. In our view, adopting a consensus-based decision model for council approvals of specific research programs would not solve the challenge of interagency coordination. Expeditious decision making requires a voting mechanism. We suggest that the council be composed of representatives from the six Federal regulatory agencies and perhaps the four Federal research agencies; each agency would get a single vote. Council decisions to endorse a proposed research program would require a supermajority of at least 60 percent of the voting council members. The council could meet quarterly to make such decisions.
4. **Decision Framework**: Although the council would be free to define and approve a risk research agenda based on its own identification of priorities, it would be useful to have an independent science assessment to work from. To that end, existing lists of research priorities should be compiled and subjected to an expedited, four-month peer review. Responsibility for the review should be given to an independent group such as the National Research Council. The independent science group would deliver a critique of the literature to the council, which would then incorporate the feedback into its deliberations. The independent science group — which

would not be a voting member of the council — would also be given the biennial task of reviewing the state of the literature on EHS risk research and providing updated, comprehensive, and prioritized assessments of research needs for the council's consideration. The first such biennial review would be delivered 18 months after the council begins operating.

5. **Federal Advisory Committee (FAC)**: A FAC should be formed, pursuant to the Federal Advisory Committee Act, comprising representatives from industry, interest groups, and academia. The FAC would review the agenda of research programs submitted quarterly for council review. The FAC could also suggest specific research programs for the council to consider. The FAC would function only in an advisory capacity; endorsements of research programs would be made by the council, composed exclusively of Federal employees.

6. **Visibility Into the Pipeline of Nanotechnologies Coming to Market**: A research agenda informed by a view of emerging technologies can be substantially more proactive in its focus. Accordingly, the council should oversee efforts to monitor the pipeline of new nanomaterials. With procedures in place to protect trade secrets, techniques might include the following:

   - Close monitoring of premarket notifications under relevant statutes such as the Toxic Substances Control Act.
   - Aggressive efforts to monitor the professional literature and industry conferences.
   - Making early sharing of new product concepts a condition of funding for recipients of the more than $1 billion in Federal funding for non-EHS nanotechnology research.
   - Close collaboration with European and Asian regulators regarding products being evaluated or marketed in other countries.
   - A government-industry partnership where firms share data on products in development. (EPA's early efforts on its Nanoscale Materials Stewardship Program may be instructive in this regard.)

   Even with these measures in place, however, it may be difficult to identify nanotechnologies in late stages of development prior to commercial introduction, as firms are not inclined to share highly proprietary information at this point in the product development lifecycle. Further research is needed to determine how best to proactively get such applications of nanotechnology on the EHS research agenda.

7. **Management Support**: The council would be supported by a small management staff that would review research program proposals, identify potential duplication with other research efforts, and suggest opportunities for integrating separate research programs. Part of the staff review would entail use of the reverse engineering principle and the nanotechnology pipeline to ascertain whether research proposals were clearly relevant to priority risk management decisions. To avoid divided loyalties, the management staff would be independent of the agencies on the council.

8. **Top-Down and Bottom-Up Agenda Setting**: Proposals for research programs would originate with individual agencies (both the regulators and the researchers), the management staff, and the FAC. As described in Section 3.1, this array of stakeholders is, in the aggregate, well equipped to define a comprehensive research agenda. When coupled with the priority-setting role of the council and independent input from the NRC or similar entity, the most important research priorities will quickly percolate to the top. An attractive feature of this approach is that, while it allows for strategic top-down oversight of the research agenda, it still allows for a somewhat opportunistic bottom-up process to determine what constitutes priority research. As suggested in Exhibit 8, reflecting these design features in the management of the Federal EHS research effort for nanotechnology will go a long way toward enhancing its effectiveness.

Exhibit 8: A Bottom-up Approach Is Very Important

"I have to tell you that this area [of EHS research on nanotechnology] is so complex that I don't know of any person or a small group of people who would be smart enough to be able to identify all the risks, set the priorities, and lay out a so-called game plan. That has to be very organic."

Arden L. Bement Jr., Director of the National Science Foundation, Testimony Before House Science Committee, September 21, 2006

As to the optimal location within the Federal government for the Nanotechnology EHS Research Council, it is important to first finalize the design features that make up the national research function. The pros and cons of housing the council at different agencies can then be assessed.

4. Managing Research Effectively: Is Research Completed in a Timely, Policy-Relevant, and Cost-Effective Manner?

Identifying a roster of research projects is only a first step. The national research program must also reliably deliver quality results on time and within budget. In Section 4.1, we first lay out some guiding principles for doing so and then in Section 4.2, we present some specific options for moving forward.

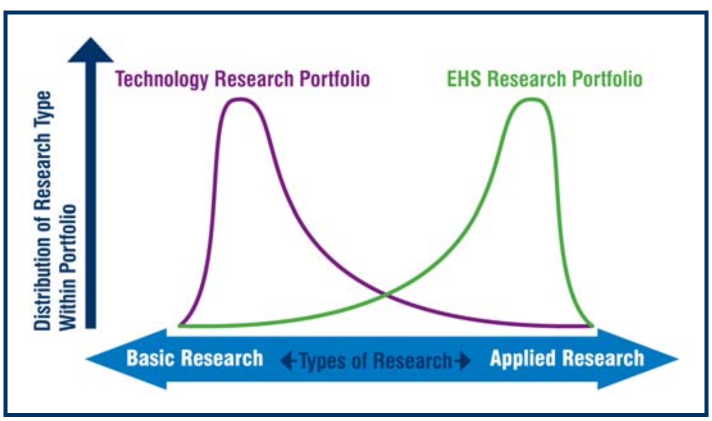
4.1 Design Principles

EHS research requires a different management strategy than technology research.

The Federal nanotechnology research initiative as a whole is broad, focusing on research both to support the development and application of new technology and to understand the EHS implications of nanotechnology. Framing these two efforts — technology research and EHS research — as separate sub-portfolios of the overall research effort is useful because each tends to focus on a different type of research and in turn requires a different management approach. Basic research is the systematic study directed toward fuller knowledge of the fundamental properties of phenomena. Applied research is the systematic study to gain knowledge or understanding to determine the needs by which a recognized and specific need may be met.[23]

As shown in Exhibit 9, we can visualize the Federal nanotechnology research program as a spectrum where the majority of technology development research is basic and the majority of EHS research is applied. Because most EHS research seeks to answer specific questions about the effects of a particular nanomaterial on human health or the environment, the EHS sub-portfolio of the research program requires specific management approaches that differ from that of the technology sub-portfolio. The design principles we recommend below reflect this belief.

Exhibit 9: Federal Nanotechnology Research Comprises Two Sub-Portfolios



The EHS research agenda must be set proactively.

The projects that make up the Federal EHS research portfolio must be selected *proactively*. This may seem obvious, but existing Federal research programs often take a somewhat *reactive* approach to setting the research agenda, in most cases, allowing the researchers considerable discretion in posing and answering specific research questions. As suggested in Exhibit 10, ultimately the research agenda needs to focus on policymakers' need for information rather than the researcher's scientific interests. This is not to suggest that all Federal research programs should operate in this fashion. Most such programs are appropriately researcher focused. The policymaker focus we suggest here is required when research is needed to address urgent science-based policy questions.

Exhibit 10: Relevance Is the Number One Criterion Identified by OMB for Federal Research Programs

> "R&D investments must have clear plans, must be relevant to national priorities, agency missions, relevant fields, and customer needs, and must justify their claim on taxpayer resources. … A customer may be another program at the same agency or another agency, an interagency initiative or partnership, or a firm or other organization from another sector or country."
>
> *Office of Management and Budget (OMB) memo: FY 2005 Interagency Research and Development Priorities, June 5, 2003.*

In reviewing several Federal solicitations for nanotechnology research, we noted that many ask broad questions only loosely anchored in the policy decisions that need to be made. For example, in 2006, NSF, EPA, and NIOSH issued a research solicitation focusing on the environmental and human health effects of manufactured nanomaterials.[24] While useful in the context of attempting to broadly define an issue, this research solicitation allowed researchers to address a range of issues including toxicology, fate, transport, exposure, and industrial ecology. EPA does afford its program offices an opportunity to review research proposals after peer review is completed, thereby enhancing the potential policy relevance of the research. In both examples, however, with researchers ultimately posing the research questions, there is a good chance that the research will not fully address the specific information needs of the policymakers.

In 2005, NIOSH outlined ten occupational health and safety issues and the specific research questions underlying them. For example, the research plan identifies worker exposure and dose estimation as one of the ten issues and identifies the following research needs:

- Determine the fate and persistence of nanomaterials in the body
- Quantitatively assess exposures to nanomaterials in the workplace, including dermal and inhalation exposures
- Determine the factors influencing the generation, dispersion, deposition, and re-entrainment of nanomaterials in the workplace

The research plan goes on to identify the other nine significant issues and outline the research needs within each.[25] This type of proactive approach should be considered by all Federal agencies that fund nanotechnology EHS research. Another good example is a 2007 research solicitation that is somewhat more focused than earlier solicitations, with EPA, National Institutes of Health (NIH), and Centers for Disease Control and Prevention (CDC) specifically seeking proposals on the physicochemical principles of biocompatibility and toxicity of manufactured nanomaterials.[26]

The dialogue between researcher and sponsor needs to be enhanced.

When it comes to research into the EHS implications of nanotechnology, it is important that the researcher and the solicitor of the research collaborate during the research process. During the execution of research under a typical Federal grant, communication between parties consists of the issuance of the grant, annual updates on the research, and the delivery of a final paper or presentation. The arms-length relationship between researcher and sponsor is exemplified by the recent EPA, NIH, and CDC joint solicitation mentioned above which makes clear that "as an applicant, you will be solely responsible for planning, directing, and executing the proposed project."[27]

Instead, policymakers should be more actively involved in the research, enabling them to both understand the research and maximize its ability to inform key policy decisions. By monitoring and staying closely involved with the research process, the policymaker also can proactively use new results to help shape future research that will be policy relevant. This more collaborative approach need not (and must not) undermine the integrity of the scientific process. Rather, an ongoing dialogue between researcher and policymaker can be expected to maximize the return on the Federal government's investment in the research.

To the degree, however, that Federal project managers become more substantively involved in overseeing the dozens, or even hundreds, of Federally supported research projects, resource constraints may become a real challenge. What's more, even if more budget resources are made available to agencies, ceilings on the number of staff may limit their ability to provide a sufficient number of qualified Federal project managers. This issue is not addressed further in this paper, but merits further attention.

The EHS research effort must be expedited and completed in a timely manner.

Given the urgency of the national research effort, completing EHS research expeditiously is imperative. The proposed schedule for delivery of scientific findings should be an explicit criterion in the evaluation of research proposals. The credibility of claims of the ability to deliver results within a certain timeframe must, of course, be considered during the evaluation, but in the context of the EHS implications of nanotechnology, research solicitors should place a premium on shorter schedules. In addition, the solicitation and evaluation process must account for the tradeoffs between project length and the certainty of results. Perhaps an additional year of research might only slightly reduce the error term of a quantitative result and, from a policymaker's perspective, may not be worth the additional time. Conversely, it simply may not be possible to answer a key policy question without a scientific research project that spans several years. The bottom line is that the tradeoff between schedule and scientific certainty must be made explicit and proposal approval decisions made accordingly.

The research solicitor and researcher should also agree on interim deliverables throughout the project. This will stimulate collaboration and enable the solicitor to understand the research as it is occurring. Ongoing deliverables also will underscore the importance of adhering to the project schedule. In many cases, the inherent uncertainty of the scientific process has led to Federal funding policies that are relatively flexible with respect to schedule. For example, one research grant program usually issues grants for an initial three years of study with the option for up to three additional years, pending approval in one-year increments. Researchers seeking extensions during project execution find that first-year extensions are almost always granted and the second year nearly as easy. (A third-year extension is rare, and permission is difficult to obtain.)[28] This flexible approach to scheduling makes sense in many situations, but given the need for prompt scientific answers to many key EHS issues in nanotechnology, it may be inappropriate for nanotechnology grants for applied research.

Quality research must be delivered in a cost-effective manner.

The urgency of nanotechnology EHS research and the need for expedited results might create pressure to cut corners when it comes to quality assurance or cost control. Though a basic principle, the importance of cost-effectively managing a limited budget cannot be overstated. Whether the Federal budget for nanotechnology EHS research remains unchanged or is increased to over $100 million per year, responsible stewardship of taxpayer resources demands that resources be allocated as cost effectively as possible. Research funds must be used efficiently, and the return on investment must be maximized by ensuring that research results are as valuable and high quality as possible. In June 2003, OMB identified two key criteria for ensuring the quality of Federal research efforts:

- Programs should award research projects through a competitive, merit-based approach.
- Program quality should be evaluated periodically through retrospective expert reviews.[29]

Adherence to a competitive, merit-based selection process will ensure that the Federal EHS program selects the most creative research proposals submitted by the highest quality researchers. Instituting retrospective expert reviews would strengthen the quality of the data produced. Together, both of these criteria could go a long way toward ensuring the success of the program.

4.2 Design Options

Designing a successful research program requires determining who should conduct the research and how it should be funded. The following is a brief discussion of the options in both areas.

Who is eligible to participate in the research effort?

A number of groups may be eligible to submit proposals in response to a Federal solicitation, including industry, academia, contract researchers (both for-profits and nonprofits), and other Federal agencies conducting intramural research. Currently, the pool of eligible candidates depends on the Federal agency requesting the research. For example, EPA typically restricts research to nonprofits and academic groups, while NIH generally also allows for-profit companies to participate. Deciding who is best suited to conduct nanotechnology EHS research requires consideration of who can best produce quality results in a timely manner.

The Federal nanotechnology EHS research program should be open to all potential researchers. This approach enables the research solicitor to choose the most appropriate researcher to complete the job. Considering the possible increase in funding and a subsequent increase in the number of projects, allowing the widest pool of researchers possible builds inherent flexibility into the system. Exhibit 11 presents some of the advantages and disadvantages of each potential research group.

Exhibit 11: Pros and Cons of Different Research Groups

Research Group	Advantages/Disadvantages for the Nanotechnology EHS Research Program
Academia	*Advantages:* Results are creative, rigorous, and original; low public perception of research bias; highly credible results. *Disadvantages:* Perception that academic researchers prefer to work without significant solicitor interaction; preference to develop and answer self-selected research questions; difficult to ensure that research will be completed quickly.
Federal Agency Intramural Research	*Advantages:* Serves the broad public interest; typically motivated to address key policy issues; some Federal laboratories are exceedingly well qualified to conduct cutting-edge research. *Disadvantages:* Potentially limited by budget resources or staff capabilities; perception that scope of Federal research can be limited by policy agendas.
Nanotechnology Industry	*Advantages:* Can focus EHS research on the specific nanotechnology products being produced; strong incentive to complete research quickly. *Disadvantages:* Perception that research may be biased or self-serving; Federal agencies may have to establish confidentiality agreements to receive proprietary information; smaller companies may not have the budget or personnel to conduct EHS research.
Contract Research Institutions (For-Profit and Nonprofit)	*Advantages:* Used to working on client-driven projects involving frequent collaboration with research sponsor and firm deadlines; sponsor can alter research focus if needed. *Disadvantages:* Perception that contractor's research could be biased by the needs of the client or work for other clients.

How will funding be awarded?

A Federal research program has three options for awarding funding: contracts, grants, and cooperative agreements. The choice of funding mechanism typically varies from agency to agency. In each case, the ultimate goal is the same, but the ability of the solicitor to set the research agenda and the level of collaboration between researcher and solicitor can vary substantially. For the Federal EHS research program, the goal should be to choose a funding mechanism that encourages active management, increased collaboration, and a high level of flexibility for the research solicitor. Exhibit 12 presents some of the advantages and disadvantages of each funding mechanism.

Research contracts can be an ideal funding mechanism for the Federal nanotechnology EHS research program. They necessitate that the solicitor identify specific applied research questions, and they encourage interaction between the researcher and solicitor, which enables the solicitor to inform the research and maximize its ability to inform policy decisions. In its endocrine disruptor screening program, EPA used research contracts effectively to conduct much of the research. EPA officials based their decision to use contracts on the need to develop specific and validated screening and testing methods and urgently address the impending requirement for assessments of the endocrine activity of chemicals under the Food Quality Protection Act.[30]

That said, the Federal EHS research effort should not rely too heavily on one type of funding mechanism for all research. Contracts may have the unintended consequence of causing research solicitors to ask inordinately narrow questions. Although solicitors, in most cases, know best which research questions are most policy relevant, they still need basic research to inform their decisions; therefore, research grants should be used as well. This scenario affords researchers the opportunity to understand basic EHS concepts that will lead to more pointed, applied research questions in the future.

Exhibit 12: Pros and Cons of Different Funding Mechanisms

Funding Mechanism	Advantages/Disadvantages for the Federal EHS Research Program
Research Grants	*Principle:* Research grants are typically issued in response to a broad, general research question and are the typical funding mechanism for research sponsored by the Federal government.
	Advantages: Long, established track record of using grants to conduct research through the Federal government; relieve solicitor of the need to have detailed knowledge to frame narrow research questions. *Disadvantages:* Do not encourage collaboration between the researcher and the solicitor; allow the researcher, not the solicitor, to choose the research questions; geared more for basic research and not as useful for applied research.
Cooperative Agreements	*Principle:* Cooperative agreements are essentially research grants with the added stipulation of increased collaboration between researcher and solicitor.
	Advantages: Increased collaboration between researcher and solicitor; enable the solicitor to establish more stringent goals and deadlines. *Disadvantages:* Geared more for basic research, not the applied research needed under the EHS program; increased collaboration requires staff to engage researchers, which may be a constraint for some agencies.
Research Contracts	*Principle:* Research contracts are typically used to answer specific research questions.
	Advantages: Encourage collaboration between the researcher and the solicitor; enable the solicitor to establish goals and deadlines; enable the solicitor to ask specific research questions and have more control over final products. *Disadvantages:* Increased collaboration requires sufficient number of qualified Federal staff to engage researchers (may be a constraint for some agencies); put pressure on solicitor to have sufficient scientific insight to frame research questions.

5. Applying Research Effectively: Is the Research Disseminated Broadly and Used to Enhance the Quality of Risk Management Decisions?

The value of any research program is realized only when its results are disseminated and used to advance the state of knowledge in a field. The national EHS research effort is no different. The key is designing a knowledge management program that effectively disseminates information to the appropriate parties in a way that facilitates use and application. Effective communication not only enhances risk management decisions but also facilitates using the completed research to inform the next round of research questions. The following sections describe the principles underlying knowledge management for the EHS research program and identify some specific options for implementation.

5.1 Design Principles

An ad hoc approach to knowledge management does not maximize the return on the Federal investment in EHS research.

The current knowledge management approach of the Federal nanotechnology EHS research effort falls short of fully informing the decision-making process. The fundamental challenge is that many disparate groups are conducting EHS research on nanotechnology, each has its own research agenda, and each produces and disseminates its own results. Currently there is no central place for interested stakeholders to visit that will enable them to easily access the details and the results of EHS research on nanotechnology.

The NNI produces an annual report summarizing nanotechnology research activities being completed by its member agencies, including EHS research. In addition, the NEHI Working Group recently released a report on Federal EHS research in nanotechnology. These reports, though useful in providing a broad overview of Federal research activities, present only brief details on individual projects and offer no indication of their scientific findings. Individual agencies also release information generated by the research they fund, but such efforts are not comprehensive and often leave the primary burden of ongoing information dissemination to grantees when they seek publication in the literature.

It is possible to track down information by visiting the nanotechnology-devoted Web sites of the various Federal agencies; however, the types of information available on these sites vary significantly, and attempts to dig deeper into a specific issue often turn into a long, frustrating search. The NNI maintains a page on its Web site devoted to EHS issues, but beyond a few introductory paragraphs, the page's main purpose appears to be providing links to the individual Federal agency sites.

Some groups, such as the Project On Emerging Nanotechnologies[31] and the International Council of Nanotechnology,[32] are already working to establish research repositories using the Internet as a portal; however, this bottom-up evolutionary approach to information dissemination falls short of meeting the goal of a comprehensive research library from which information is actively distributed.

In short, information dissemination falls victim to the same problems as the EHS research program as a whole: a lack of a strong, well funded coordinating body that makes full use of the latest technologies available for disseminating information. Aside from the policymakers who have access to data generated for their own agencies or those who are aggressively tracking research occurring elsewhere, Federal EHS research has the potential to go undelivered to those who need it.

A centralized state-of-the-art knowledge management system can ensure effective and timely dissemination of information to researchers, policymakers, and the public.

An effective knowledge management program creates an information forum where a marketplace of ideas can flourish. Increasing the availability of existing and ongoing research results and creating open dialogues between researchers and policymakers can create an environment where the scientific process — the testing of hypotheses, the replication of experimental results, and the development of theories — can openly feed the risk assessment process. An effective knowledge management system also can serve to expedite the research, since it can reduce what economists call "transaction costs" and move needed information from supplier to consumer much more quickly than a series of ad hoc efforts to disseminate information.

Clearly defined oversight, therefore, must be established with the goal of cataloging and managing all of the existing EHS knowledge and all new knowledge as it is created. That information then should be accessible to the entire research community, the public, and policymakers. Additional functions should include drawing linkages between studies, identifying key gaps in the existing knowledge base, and ensuring that EHS information is available to those who seek it.

5.2 Design Options

When it comes to developing a knowledge management system, two basic decisions need to be made. The first addresses who will manage the system, and the second focuses on how the knowledge will be collected and disseminated.

Who will be responsible for managing the system?

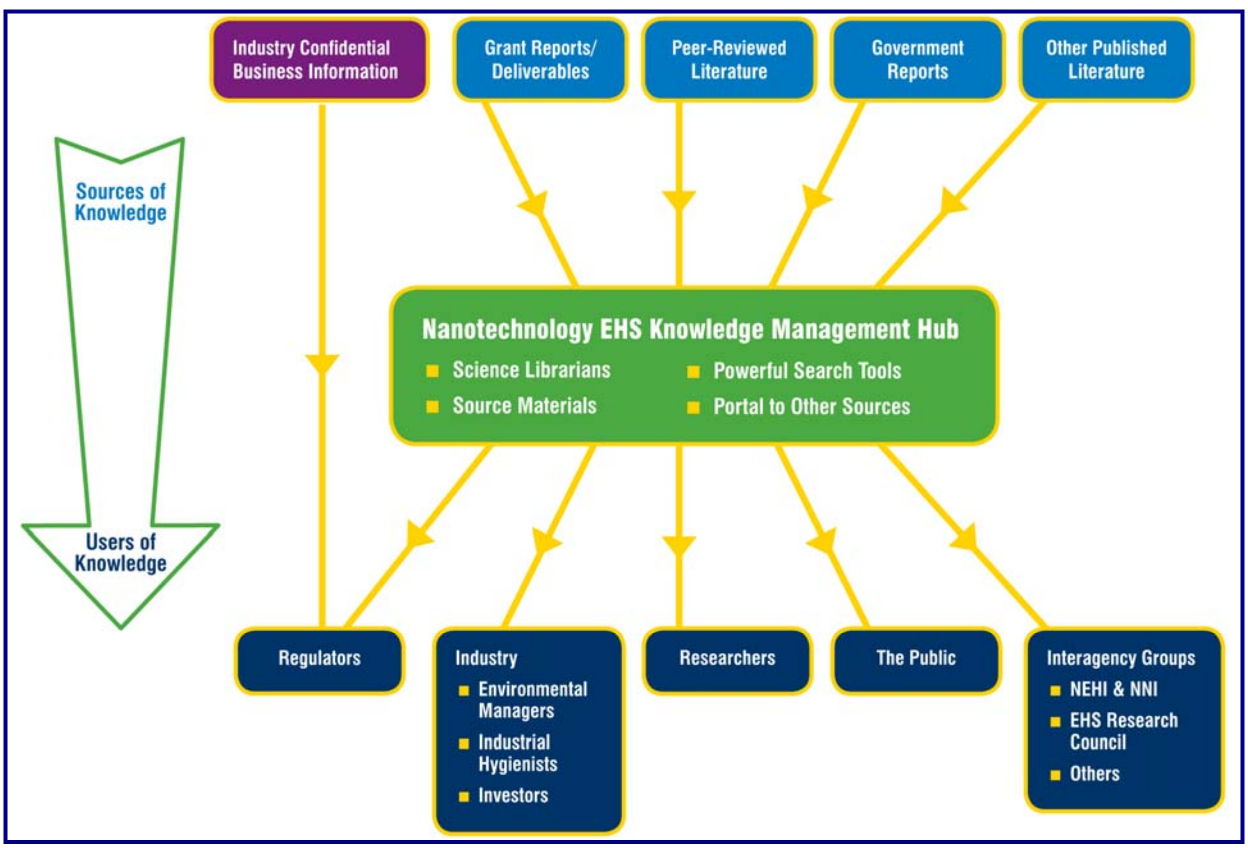
Finding a home for the knowledge management system requires determining which Federal agency or other group is well positioned to manage the effort. A good organizational home for the knowledge management system would be one with the following characteristics: an established track record of performing similar functions; the capabilities and competencies to do the job well; and the established business processes and information technology tools to be able hit the ground running. Creating a new organization to operate the knowledge management system would take longer and likely produce a less satisfactory outcome than turning to an existing entity with the requisite qualifications.

The requirements of the system should be fully defined before choosing the specific agency to oversee it. Many features could be built into a knowledge management system. Depending on which are selected, different agencies may be more appropriate to the task. Irrespective of which entity takes the lead in operating the knowledge management system, it must work closely with the Federal Nanotechnology EHS Research Council described in Section 3.

How will the knowledge be collected and disseminated?

To be effective, the knowledge management system must provide a comprehensive bridge between the sources of information and the users of that information. In this sense, the knowledge management system can be seen as a hub, pulling in information from researchers and other sources, compiling and organizing the information in a coherent fashion, and pushing it out to those who need it. In short, its mission must be viewed as the proactive movement of information from those who generate it to those who will use it. Exhibit 13 illustrates how a knowledge management hub for nanotechnology EHS research might work. The use of the word "hub" is intentional; an effective knowledge management system is central to virtually every aspect of the national effort to fully characterize the EHS implications of nanotechnology.

Exhibit 13: Knowledge Generated by EHS Research Must Be Managed Proactively



At the heart of the system would be a team of trained science-oriented librarians, the collected source materials, powerful search tools, and a portal to other sources of information from outside of the Federal research effort. Collected source materials would include Federal and non-Federal research results, available both domestically and internationally. In addition to managing the hub, the team of librarians would be responsible for producing newsletters, holding workshops, and working directly with policymakers, updating them as research results are received.

As noted in Section 8, the critical next step in the launch of a knowledge management system is the identification of specific design requirements in far greater detail than shown here. Once such requirements are specified, policymakers can determine the appropriate organizational home for the knowledge management system, its operating procedures, and the resource requirements for the program.

6. Ensuring Continuous Improvement: Is Ongoing Feedback About the Quality and Utility of the Research Used to Enhance the Nanotechnology EHS Research Function?

The Federal officials responsible for the design and implementation of a national EHS research strategy have an important public mission. They must guide research efforts in ways that promptly identify and illuminate with sound science the key risk management issues associated with nanotechnology. In addition to this responsibility is the obligation to taxpayers to wisely steward the tens of millions of dollars being invested in nanotechnology-related EHS research. For both of these reasons, Federal policymakers need to ensure that the national EHS research effort is subject to continual review and improvement.

We have identified certain principles that should guide the design of an iterative feedback system that would be applicable regardless of the specific mechanisms and business processes that make up the EHS research program. Section 6.1 reviews these principles, while Section 6.2 addresses some of the specific design options that could be made part of the national research program.

6.1 Design Principles

Nanotechnology is a fast-evolving field; research efforts need to be flexible and adaptable.

Two important factors necessitate that the national nanotechnology research strategy be built on adaptive principles. First, the underlying technologies are evolving rapidly. New discoveries, successes in moving from laboratory to manufacturing, and innovation in the application of nanotechnology create conditions of constant change. This dynamic environment has profound implications for the EHS research program because it can affect the intrinsic hazards of and potential exposure to nanomaterials. The research agenda must anticipate the commercialization of specific nanomaterials and continuously adapt the research focus to those nanomaterials that emerge from the laboratory. In addition, as researchers identify new uses of nanomaterials in different applications, they need to revisit exposure scenarios to assess their continued validity and relevance to the new uses.

The second factor necessitating an adaptive strategy is the evolutionary nature of EHS research itself. As results come in, new research topics will become important. If researchers discover that a new nanomaterial poses a relatively high hazard, additional research into the efficacy of engineering controls may become important. If research shows that a particular nanomaterial can readily pass through the skin, then further study into the consequences of dermal exposure may be necessary. Because successive waves of research will build on the results of previous efforts, the national strategy must contain mechanisms for extracting key findings of relevant research and ensuring that they are used to frame the next waves of research.

The national EHS research strategy should reflect lessons learned from other Federal research programs.

The Federal effort to understand and characterize the EHS risks associated with nanotechnology is not the first such undertaking. As shown in Exhibit 14, the Federal government has undertaken several initiatives aimed at developing and applying sound science to important policy decisions. In addition, as noted in Section 3.1, the National Research Council previously supported EPA's airborne particulate matter program with an independent scientific assessment of risk research priorities.

Exhibit 14: Well-Performing Research Programs Can Provide Valuable Lessons Learned

Using the Program Assessment Rating Tool (PART), OMB and Federal agencies jointly assess the performance and management of Federal programs and identify areas for improvement. A three-star rating of "Effective" is the highest rating. The following Federal research programs are among those that have earned this rating:

- NSF's Fundamental Science & Engineering Research Program
- DOD's Defense Basic Research Program
- NIH's Extramural Research Programs
- NASA's Astronomy & Astrophysics Research Program
- USGS's Geographic Research, Investigations, Remote Sensing Program

Given their high PART ratings, these programs may be especially good models for identifying lessons learned that are applicable to the national nanotechnology EHS research effort. More detail is available at www.whitehouse.gov/omb.

Although not all aspects of such programs are directly relevant to the design and operation of a nanotechnology EHS research effort, they offer a wealth of lessons about what works and what doesn't — both at a broad strategic level and at the day-to-day operational level. Studying these analogous programs and extracting the relevant lessons can make a material difference to the success of the national EHS research strategy.

OMB guidance on using its Program Assessment Rating Tool also might prove useful. The guidance explains that evaluations of Federal research and development programs should be built around three specific investment criteria: relevance, appropriateness, and quality. The OMB guidance also provides several sub-criteria to use in the evaluation of Federal research programs such as the effort to research the EHS implications of nanotechnology.[33]

6.2 Design Options

Policymakers have several options for enhancing the flexibility and adaptability of the research strategy as they implement it. All are premised on the belief that continuous reviews and feedback from ongoing activities are prerequisites for obtaining the highest value from the national investment in EHS research. Put simply, enough is not known at this time, nor is there sufficient foresight into the future, to set a course for research management that won't change. Six design features may prove particularly important to ensuring an adaptive approach.

1. **Policy relevance**: Tightly linking research activities and policy debates will go a long way toward ensuring that research evolves in ways that continuously inform the policy process. Prior to funding any EHS research, proponents must be able to explain how the study results would be relevant to efforts to craft prudent policies related to nanotechnology. If they cannot identify a relevant policy issue that their research would help resolve, then the project should be given a much lower priority for funding.

2. **Commercial relevance**: Another way to maximize continuous improvement is to link the research agenda to the commercialization of new nanotechnologies. EHS research needs to focus on those technologies and materials to which workers or consumers may be exposed or that might be released in the environment. Beyond ensuring the health and safety of research personnel and addressing waste management issues, there is little need for research into technologies that are unlikely to leave the lab or be introduced into commerce. The concepts for ensuring visibility into the pipeline of emerging nanotechnologies that were discussed in Section 3 are important to ensuring the ongoing relevance of specific research initiatives.

3. **Prior and parallel research**: Continuous improvement in the research function requires a firm connection between the results of one wave of research and the launch of the next generation of studies. Proactive management by the council described in Section 4 will be important in this regard. As research projects near completion, the council should review the implications of the results to identify the logical next line of inquiry (assuming one exists). Rather than waiting for a proponent to step forward and take on the new research, the council should push for the next wave of research. Similarly, the council should watch for parallel research efforts, looking to combine them and reap economies of scale or to satisfy itself that sound scientific reasons exist to keep parallel efforts distinct.

4. **Internal reviews**: Performance measures should be established for all three phases of the research program. Starting with the primary objectives of each, program designers need to identify the outcomes and results that will achieve those objectives, and in turn, the specific activities and outputs that will drive the outcomes and results. Metrics should be established and monitored for all aspects of the program. Regular internal reviews should be scheduled so that operation of the research program can be continuously tuned up and optimized. The Government Accountability Office, for example, has defined a best practice for Federal research programs as the "expert review of the quality of research outcomes … that evaluates:

   (1) The quality of current research as compared with other work … in the field,
   (2) The relevance of research to the agency's goals and mission, and
   (3) Whether the research is at the 'cutting edge.'"[34]

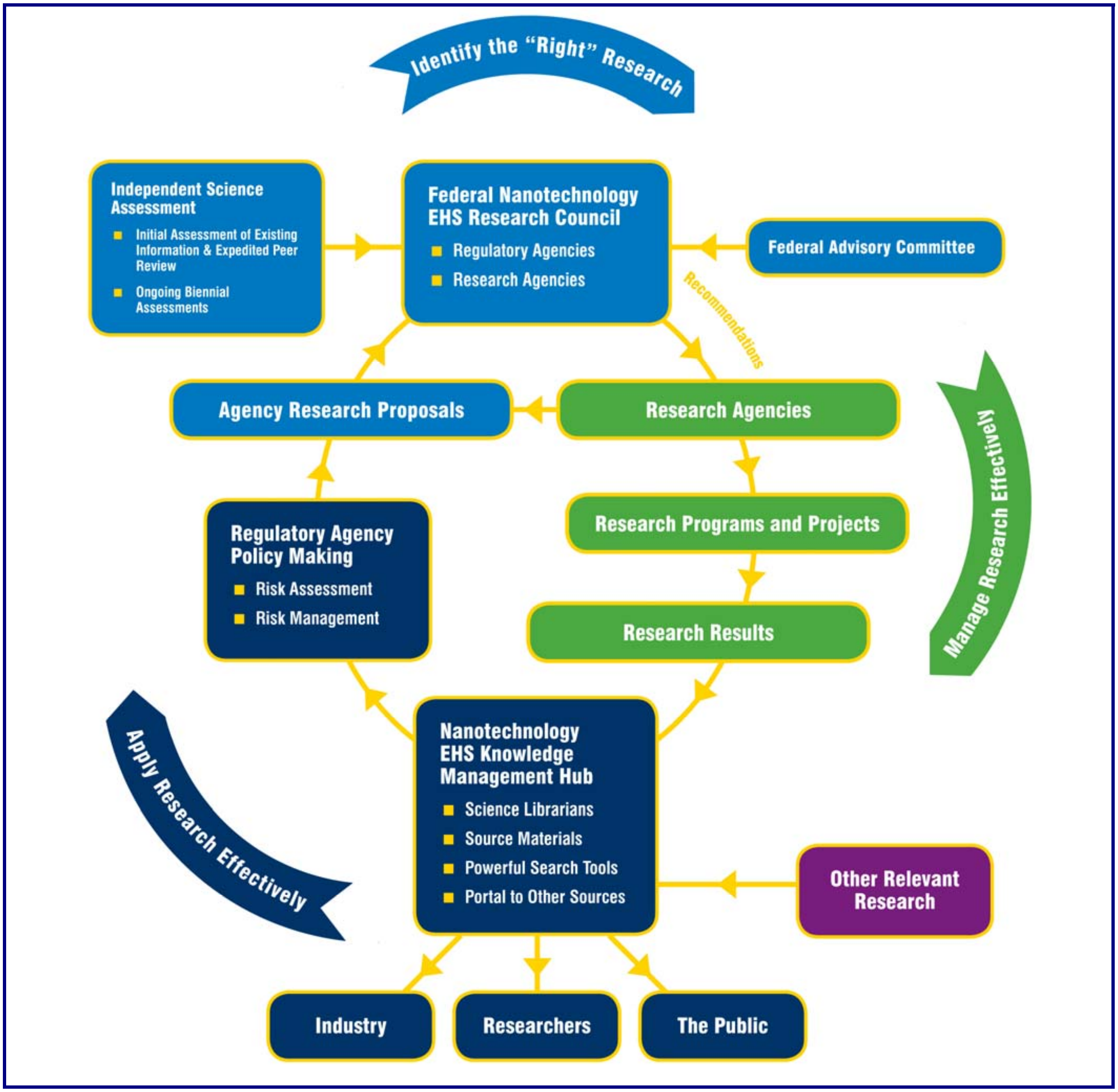
5. **External reviews**: To provide fresh perspectives not offered in an internal review, the council should invite periodic outside reviews of the operation of the nanotechnology EHS research program. At a minimum, the National Research Council could provide such perspectives during its triennial reviews of the National Nanotechnology Initiative as required by the 21st Century Nanotechnology Research and Development Act. The Government Accountability Office might also be a good candidate to conduct reviews and offer recommendations for improvements.

6. **Sunset provisions**: Although the nanotechnology field is currently going through rapid change, and the EHS agenda is lengthy, this may not always be the case. As the industry matures and EHS research yields answers to key policy questions, the need for a national research program of the size and scope contemplated here may wane. It therefore seems prudent to build in a sunset provision. After perhaps ten years, the authority and funding for these efforts might automatically lapse. That is not to say that all research would be finished in 2016 and that the Federal role would end; rather, the sunset provision is a mechanism for ensuring that a debate takes place about the appropriate approach on a go-forward basis.

7. Bringing It All Together: An Integrated Perspective

As explained in Section 2, maximizing the value of the national investment in EHS research on nanotechnology requires a holistic and integrated view of its component parts. Not only must each element of the national effort be well designed and executed, the elements must fit together in a coherent way and interoperate effectively. Sections 3 through 6 reviewed several specific program elements and Exhibit 15 below shows the integration of those elements into a complete management framework. We believe that moving forward under this, or a similar, framework can expedite the process of supporting the development of nanotechnology while taking prudent steps to protect human health and the environment.

Exhibit 15: An Integrated EHS Research Framework Will Maximize the Value of the Federal Investment



8. Areas for Additional Investigation

Several areas for additional research and investigation could yield insights valuable to the design and implementation of a national EHS research program. Some of the more important ones are briefly described below.

- Compile existing proposals for the EHS risk research agenda and subject them to expedited peer review by an entity such as the National Research Council.
- Further develop the framework for establishing the proposed Nanotechnology EHS Research Council.
  - Identify and evaluate options for housing and staffing the council at alternative Federal agencies.
  - Develop the business processes, structure, and organization of the council.
  - Further characterize the mission and function of Federal agencies involved in nanotechnology research and determine appropriate representation on the council.
- Define the design requirements for a Federal knowledge management system and investigate the degree to which existing databases and Web portals for nanotechnology EHS research can be adapted as the tool of choice. Determine the appropriate organizational home for the knowledge management system.
- Engage regulators and researchers in other countries and multilateral bodies such as the Organization for Economic Cooperation and Development to identify areas of potential synergy and collaboration, thereby maximizing the Federal return on its research investment.
- Characterize lessons learned from other Federal research programs and assess their applicability to researching the EHS implications of nanotechnology.
- Identify methods for allowing visibility into the pre-commercialization pipeline of nanotechnology-based products so that appropriate EHS research can be launched proactively. In particular, address issues of trade secrecy and data availability.
- In light of the recommendation to involve Federal research sponsors more deeply in specific research projects (to enhance the policy relevance of these projects), estimate the new workload and address staffing issues related to the number and capabilities of individuals qualified to serve as research managers for Federally sponsored research projects.

Endnotes

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