

NanoReg Report

January 31, 2007

Interview with ICF International

The [NanoReg Report](#) conducted an exclusive interview with [ICF International](#) to discuss the recently released report, *Characterizing the Environmental, Health, and Safety Implications of Nanotechnology: Where Should the Federal Government Go From Here?*

The report, prepared prior to the federal government's request for input on the nanotechnology EHS research priorities, provides a framework for a research program with a comprehensive approach and specific recommendations.

With many aspects to the debate, ICF has provided leadership and insight that the federal government should take to heart.

NanoReg Report: What brought you to the decision to prepare this report?

ICF: To set the context, ICF has been involved in the environmental policy arena since the very early 1970s. To maintain our position as one of the leading environmental consulting firms, it's incumbent upon us to stay abreast of the developments in the field. We looked forward and saw that the emerging field of nanotechnology was one that was going to potentially pose significant environmental health and safety (EHS) issues, and thought that the competencies that ICF has would be very relevant to helping the nation address those EHS issues.

We thought it was important to come to that discussion with some intellectual substance, some real – though it's an overused word, we think it's apt in this case – thought leadership. And we asked ourselves, if we were in the shoes of a public policy official or a corporate EHS official, trying to deal with nanotechnology's EHS implications, how would we want to think about it? What would be a holistic, comprehensive integrated framework for thinking about it?

We talked to a lot of the folks in the firm with experience in that area. And, because we believe that it's important that our work be grounded in the real world, we went out and interviewed several stakeholders in the nanotechnology arena and then pulled together the framework described in the paper.

NanoReg Report: You mentioned some of interviews you were able to conduct. Can you give me an example of some of the experts you were able to consult with in preparing the report?

ICF: We talked to a cross-section of people. We talked to folks up on Capitol Hill, the House side and the Senate side. We spoke with officials in the Executive Branch, as well as folks in the corporate sector and the NGO sector, as well.

NanoReg Report: When you were preparing this report, were you surprised that no one had really done this yet?

ICF: We were in the audience at that September 2006 House Science Committee hearing, at which the latest federal research strategy document had been released. Both the Republican and Democratic leadership of that committee expressed an awful lot of concern about the state of the federal research agenda.

That's when we first thought that there might be a gap in the public discussion. We tended to agree with the Members and some of the witnesses who found the report a good piece of work, but felt it didn't go far enough in terms of prioritizing the areas that needed the most research, and that it didn't really lay out a game plan for getting there.

We are very sympathetic to the difficulty of the task at hand, which is that you have at least a half dozen federal agencies engaged in research and development on nanotechnology in the EHS area.

It's very difficult in that interagency environment to actually move forward with a single cohesive policy, and some of the toughest nuts to be cracked here are crafting and implementing a research agenda in the interagency environment. If this all fell within the purview of a single agency, it would be a lot easier, because there would be one set of decision makers, one set of congressional folks who were interested, and one entry-point for external stakeholders who need to be involved. That it's spread the way it is across the federal government makes it much more cumbersome.

NanoReg Report: Should the National Nanotechnology Coordinating Office (NNCO) be playing a greater role in managing the EHS research program?

ICF: There's an important role for the NNCO to play here. But it's important to keep in mind that they are constrained along several dimensions. First of all, their staff appears to be in the single digits. Directing the EHS research agenda is only a small piece of

what the NNCO is ultimately responsible for. The NNCO does not control budgets, so they can't decide to move a piece of the \$1.3 billion aggregate budget from one agency to another to conduct some research – they don't have the budgetary authority.

Nor do they have the direct line authority over those agencies. They can only suggest what agencies might do. They can convene meetings at which agencies talk to one another. But it's quite difficult for the NNCO, at least as it's structured now and at the level it's funded at now, to do more. You'd have to go back and look at its funding levels and its authorities if you wanted NNCO to play a stronger role.

NanoReg Report: You bring up an interesting point about funding. There's been a lot of discussion about how much money should be spent on EHS research, the proportion of it, perhaps, being smaller than many stakeholders would like to see of that \$1-plus billion, that, depending on who you talk to, anywhere from \$10 to \$40 million going toward EHS research. How are we going to face this challenge with a relatively small EHS research budget?

ICF: There are two ways to get it wrong when it comes to EHS research. You could assume that nanotechnology is essentially benign and allow its widespread introduction into the marketplace, only to discover 10, 15 years later a situation like DDT or asbestos or lead or CFCs and really regret that we didn't stop the products from coming to market.

The converse is also true. We could assume that nanotechnology is extremely hazardous and block its introduction into the marketplace, and, in the process, deny ourselves all its benefits. The potential benefits of nanotechnology are huge, whether it's in medicine, energy efficiency, information technology or environmental protection.

Those are two different kinds of mistakes we might make. What they share in common is the feature that good solid EHS research done now lowers the probability of both kinds of mistakes. If we can get clear insight into the true risks that are posed by nanotechnologies, we can regulate in situations where they're dangerous, and we can allow their introduction into the marketplace where they're not, and get an optimal mix of the two. But it seems to us that in a vacuum of information, the likelihood of both kinds of mistakes goes up pretty significantly. Such mistakes have real economic consequences that justify a greater investment, now, in EHS research related to nanotechnology.

NanoReg Report: The Food and Drug Administration (FDA) has expressed concern about its authority to regulate some of the materials in consumer products. Do you see that as a major challenge for them?

ICF: It's a challenge that goes beyond FDA. There are regulatory programs in place that predate the introduction of nanotechnology and didn't anticipate some of their unique characteristics. Cosmetics were never really seen as a source of great risk. The kind of unique health hazards potentially posed by nanotechnology in cosmetics is not something that FDA has a great deal of experience with – they certainly don't have premarket regulatory authority over cosmetics. They do have some aftermarket regulatory authority, but it is fairly limited authority.

You could also look at the Environmental Protection Agency (EPA), where, under the Toxic Substances Control Act, there are some exemptions that made sense 20 years ago, where if chemicals were produced below a certain volume they're exempt from some of the premarket requirements. But with nanoscale materials being produced in such small quantities, the exemption perhaps should be rewritten in terms of surface area, particle count or some other unique characteristic of the nanomaterial.

There are undoubtedly other examples where the regulatory structures may not be up to the task of covering nanotechnology adequately.

NanoReg Report: The report suggests four objectives for the policymakers including the importance of addressing the “right” research. Can you give some background on what is meant by the “right” research?

ICF: It's very helpful to ground this discussion in the first principles of risk management. And ultimately what we're asking policymakers to do here is make sound decisions where they trade off the benefits and the costs, the risks and the value of nanotechnology. To make those risk management decisions, we typically do risk assessments, where we scientifically categorize the likelihood and severity of different scenarios that may come to pass.

In order to enable the risk assessments, we need to have the underlying risk research that's been done to support the risk assessments, whether it's how these particles behave in the environment, their effect on human health, or the effectiveness of engineering controls at keeping exposures down to an acceptable

level. Those are the risk research questions that ultimately need to serve the risk management decision.

When we talk about doing the “right” research, we're talking about research that can be turned into actionable knowledge. The research agenda should be structured so that when policymakers ask those questions the research program has generated the necessary answers.

NanoReg Report: You talk in the report about better management by the policymakers. How can they better manage the EHS research effort?

ICF: There are different techniques that one uses to manage research, depending on what the purpose of the research is. In the report we draw the distinction between applied research and basic research. It's not a real sharp distinction, it's perhaps more of a continuum.

As an example, at the applied research end of the spectrum, and we have to acknowledge Dr. Andrew Maynard for presenting this example, you could take a respirator and you could ask yourself if 50 nanometer particles of a certain type pass through the respirator, or does this respirator stop them. This is a very specific, applied question. At the other end of the spectrum, the basic research end of the spectrum, we tend to pose very broad questions intended to give us a more complete understanding of the threats of nanomaterials.

When it comes to a particular nanomaterial, responsible EHS policy requires that we think about all sorts of things, about its behavior in the environment and its decomposition or its agglomeration, who might be exposed to it, what body organs might take it up, how they might react, and what the ecological effects might be.

The task of understanding EHS risks is much closer to the applied end of the spectrum. We have specific questions that we need to get answered now about the fundamental toxicity and hazard of these chemicals, how they behave in the environment and how effective certain kinds of controls are.

NanoReg Report: You make an interesting point about management of the research. One of the suggestions in the report was the formation of a multi-agency federal nanotechnology EHS research council. How would that work?

ICF: That was an idea we suggested in the report. It was meant to be a conversation starter and our thinking has evolved somewhat since the report was issued. We have more than enough interagency bodies right now and don't we need to create a new one. However, there need to be some changes in the structure and operation of one or more of the existing groups. The Nanotechnology Environmental Health and Implications Work Group (NEHI) might be the appropriate venue for these kinds of discussions to take place.

What we're trying to do is overcome the difficulties of interagency collaboration. Rather than a loosely structured, consensus-based interagency group, we need one with a tighter organization and more clear decision rules.

What we thought might work would be a situation where specific research programs would be brought by agencies to this body to endorse or reject. And that result would be public information.

And in order to make the group's decisionmaking a more effective, we proposed a one agency, one vote policy, meaning there would be a set of agencies represented, but no matter how many individual people represented that agency, the agency would have only one vote. EPA would have a vote, OSHA would have a vote, FDA would have a vote, and for an agency's specific proposed research program to get endorsed it would require a majority vote.

NanoReg Report: You raise an interesting point about making the decision process public, and that the research program itself really needs some oversight and continuing review and improvement. Could you tell us how that would work?

ICF: We could invite outside review of the research program and the review could happen in a couple of different ways. One, it could be very central to the operation of the whole thing. An outside body, the National Research Council, or National Academy of Sciences could be asked to routinely propose what they think are the top priority research needs, and, in that sense, provide a third-party opinion about what's most important.

You could alternatively ask such a body to function only in a review capacity and to periodically look at the activities of the federal research effort and offer commentary and suggestions for improvement.

We also suggested the formation of a federal advisory committee as a way to formally allow industry and NGO stakeholders the opportunity to suggest additions to the agenda for research.

But the bottom line here is that if you include only the federal regulators and the federal researchers, you really don't have everybody you need at the table. You need these other stakeholders. Because they're not federal employees, they can't make decisions about federal funds. We have to see them in an advisory capacity to those that are custodians of the public funds.

NanoReg Report: One of the suggestions in the report is to develop an effective knowledge management system. Could you give us an idea of what is meant by that?

ICF: The field of nanotechnology is evolving rapidly. There is research being done along many different dimensions, some that are purely environmental health and safety, others that are purely around the technology and its application, and then some things that are in the middle. For example, standardization, nomenclature and the basics of particle behavior are relevant to both the technology side and to the health side. The folks trying to design the new applications need to understand exactly how these particles behave and a lot of that information is also relevant to the health risk people.

So there's lots of research being done and there are a lot of databases out there but they're still not integrated very well. What we have in mind is something much more akin to a classical library, with librarians, reference librarians, who know their subject matter and know all the databases.

The whole thing can be web-based, and can operate in a virtual sense, and it may need as few as four, five, six science-oriented librarians who are monitoring the literature and thinking about who their user community is. Though we have not studied it yet, the National Library of Medicine has been suggested as a model that we ought to look at for a very well-run, proactive, science-based library function.

One of the outputs of the knowledge management hub would be something that would communicate these risks and help clear up the uncertainty for the public. Communicating to the public is very important. Government has a role to play here in getting good science and risk information into the hands of the public.

NanoReg Report: What are the orphan issues that are mentioned in the report?

ICF: Several of the regulatory agencies have the statutory mission to manage risk and they implement their risk management programs through regulatory programs. They are constrained, though, by those statutes and regulatory programs. If a particular nanomaterial falls outside one of the programs, the agency is not naturally going to be looking at it. If, for some reason, a substance were not subject to a particular regulation, the private sector wouldn't bring it in for review, the compliance people wouldn't go out looking for a company that didn't bring it in, and it might just not be on the radar screen of the regulatory agency.

Probably the quickest example would be cosmetics, in which nanomaterials have been introduced. Because FDA has limited statutory authority and lacks a regulatory program to really oversee them, particularly in a premarket capacity, cosmetics can fall between the cracks.

The federal government needs to find a way to get visibility into the pipeline of nano-related products coming to market, so that in the event that there are real risks, they can be studied before the products are in widespread use rather than after. And some statutes have pretty strong pre-market requirements, but others don't.

There are some ways – some very simple ways if the resources are put to it – for the federal government to get insight into the pipeline. It can be as simple as being at all the trade shows and paying attention to what the industry is publishing in the journals and trade publications.

What's most important about the avoiding orphan risk issues is that when you're deciding who should be at the table to set the risk agenda, let's make sure that the people at the table have a very broad scope, and that topics being offered up for research cover the full gamut of EHS issues, not just those pieces that are subject to federal regulation under the current policy regime.

NanoReg Report: What do you hope to achieve with this report?

ICF: The intent of the report at one level was to just bring a holistic, integrated view to the consideration of EHS research strategy. Several important, valid and valuable points about this issue were being made by a lot of different people in a lot of different contexts. But, as far as we could tell, there was no framework that pulled it all together, so we decided it would be very helpful to

develop a coherent and comprehensive overview of how all the pieces might fit together.

And our intent also goes back to the reality that ICF has often been at the forefront of new environmental issues. Where we can add value is in helping to structure an issue in ways that make it more amenable to resolution. If we can frame what needs to be done and the kinds of decisions that need to be made at different points in the process, we can help inform and thereby facilitate the policy process.

Because of the positive feedback we've received on our December 2006 report, ICF will be supplementing it with a series of short policy briefs. Each brief will dive deeper into a specific topic that is especially important to the policy debate around characterizing the EHS implications of nanotechnology, including many topics we've discussed today. We will be releasing those policy briefs periodically over the next three months at our website: www.icfi.com/nano.