Using Expert Elicitation to Prioritize Resource Allocation for Risk Identification for Nanosilver

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Many of today's uses of nanotechnology and nanomaterials can comfortably fall under the current regulatory system with minor adjustments. However, the Woodrow Wilson Center's Project on Emerging Nanotechnologies has pointed out that the U.S. regulatory system is not prepared to deal with successive generations of nanotechnology and emergent technologies.[1] Nanotechnology presents a challenge. The current regulatory standards and methods are no longer sufficient to help ensure the public's safety. It is an area of high uncertainty in which environment, health, and safety information is scarce; there is no single index such as concentration to measure toxicity; standards do not yet exist; the ready environmental transport of nanomaterials can increase the chance of exposure; real-time monitoring is not available; and nanomaterials might have system-level human and environmental risks.[2] Thus, there is a need for a new and improved oversight system. Within this system there is a need for quickly assessing risks of emergent technologies so that informed policy decisions can be made.

Managing nanotechnology risks will require collaboration among multiple disciplines, including experts from science, law, medicine, and ethics. But practitioners from these different domains operate from what the historian and philosopher of science Thomas Kuhn called unique paradigms.[3] A paradigm is both a way of thinking and a way of doing; all the practitioners in a

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domain know both what problems are worth solving and what methods to use in solving them. Communication across paradigms is difficult.

When new problems emerge that do not fit nicely into existing disciplinary and expertise categories, practitioners from different paradigms will have to work together. The development of nanotechnology represents such a problem and opportunity; collaborations are necessary not only among scientists and engineers, but also with ethicists, social scientists, lawyers, policy makers, and other stakeholders. Peter Galison noted that physicists and engineers working together on the development of radar during World War II came from different paradigms and yet were able to work together, because they formed trading zones in order to exchange ideas and resources.[4] The key to the success of such a zone, in Galison's view, is gradual evolution of a common language, from a shared jargon to a creole that is a hybrid of the different disciplinary languages involved, including some new terms and concepts. New fields will likely emerge out of nanotechnology trading zones, especially where nanotechnology intersects with biotechnology, information technology, and cognitive science, as well as medicine and the environmental sciences.[5]

Gradual development of a creole is one way of facilitating exchanges across a trading zone. Trading zones are also often facilitated by agents.[6] The best agent would not only know enough of the language of both cultures to act as an interpreter, but would understand enough of their world-views or paradigms to encourage them to trade.

But how does one achieve sufficient understanding of the different cultures in a trading zone to act as an effective agent? Harry Collins and Robert Evans have solved this problem by developing expertise that is interactional.[7] Interactional expertise is the ability to adopt the language and concepts of an expertise community sufficiently to pass as a member, without being able to conduct the research. Collins's discovery of this kind of category emerges from his own experience as a sociologist of science, in which he had to acquire sufficient expertise to study scientific communities by interacting with the members.[8] Interactional expertise is not limited to social scientists; any expert who enters into the language and customs of another domain can be an interactional expert. Nanotechnology oversight will require the formation of trading zones among multiple stakeholders, often from very different backgrounds. The dialogue among them will be facilitated by interactional experts who can cross disciplinary boundaries. The end result will be more capacity to anticipate and manage the surprises on the nanotechnology frontier.

Reversibility and Adaptive Management

Management experiments have to be reversible, following one of the core principles of Earth Systems Engineering Management (ESEM).[9] If an experiment leads to a semi-permanent system change, then instead of using the result to design a new experiment, one is forced to develop a new management strategy for the changed system. Reversibility requires that one be able to return the system to the state before the experiment. Reversibility is a good heuristic to apply when thinking about the introduction of a new nanotechnology: how will we remedy the consequences if the technology doesn't work out?

But as nanotechnologies emerge, they will interact in ways that are hard to anticipate. One solution, advocated by Ortwin Renn and Mihail Roco, is the application of adaptive management to nanotechnology.[10] Adaptive management has been used to restore salmon runs in the Pacific Northwest, to maintain the Everglades, and in other situations where multiple stakeholders and different value systems must cooperate in order to preserve a resource used and valued by all.[11] In adaptive management, "policies become hypotheses, and management actions become the experiments to test those hypotheses."[12]

These adaptive management experiments will require the use of multiple research methods, including laboratory experiments, field studies, and models of historical trends that have the potential to signal systems change.[13] Choosing a combination of methods and models requires a trading zone, because more than one discipline has to be involved. The models

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and methods themselves will have to be adapted over time.

Anticipatory Governance

Trading zones emerge either outside of formal governmental and institutional structures or as a way of working around them — of cutting through layers of bureaucracy. Bureaucratic rules and institutions can emerge out of a trading zone, in order to enforce what participants agreed to. For example, regulations in the United States depend on democratic institutions and should involve consultation with multiple stakeholders, though this is not always done in practice. The costs and benefits of proposed regulations in the United States have to be quantified, and risk has to be proven rigorously.[14] In the earliest stages of technological development, the risks and benefits are not known or quantifiable, and the law of unintended and unexpected consequences comes into play. Furthermore, the degrees of freedom for modifying new technologies are greatest upstream, before the system is locked into a particular technological system. Therefore, effective oversight requires the ability to anticipate possible impacts of emerging nanotechnologies, in order to make sure governance mechanisms like regulation are adequate.[15] In the rest of this paper, we focus on one tool for anticipatory governance: expert elicitation

Expert Elicitation as a Method for Facilitating Anticipatory Governance

In risk assessment situations where information is lacking, expert elicitation is often used to fill the gaps.[16] This method involves asking experts to estimate the potential human health and ecological risks, in the light of exposure scenarios. The experts may say there is too little research to be certain, in which case they have identified a knowledge gap. Experts may also disagree on potential hazards, especially if experts come from more than one specialization.

This paper provides a detailed account of an expert elicitation regarding silver nanoparticles. In general, our approach follows standard methods in the cognitive sciences by providing in-depth, qualitative, and quantitative analyses of the views of a small numbers of experts (n=10), looking not only at their conclusions but at the rationale for their conclusions, and trying to graph their reasoning processes.[17] This methodology allows one to probe not just what an expert says, but why; a small number of participants generates an enormous amount of data.

Previous Research Involving Expert Elicitation

As reported in this symposium, a nanotechnology oversight project's Working Group organized by the University of Minnesota, consisting of experts in law, government, and academia, has used a combination of historical analysis, expert elicitation, and behavioral consensus to analyze oversight systems such as GMOs and biotechnology in the context of a larger effort to develop oversight models for nanobiotechnology.[18] Through expert elicitation and behavioral and mathematical analysis, they were successful at identifying criteria for analyzing oversight across four categories: development, attributes, evolution, and outcomes of oversight systems. The project used expert elicitation to identify the key criteria across those four categories, and then integrated those criteria into a survey instrument used for case-specific expert elicitation.

Our own experience with expert elicitation persuaded us that it is important to capture the rationale and points of contention brought up by the expert.

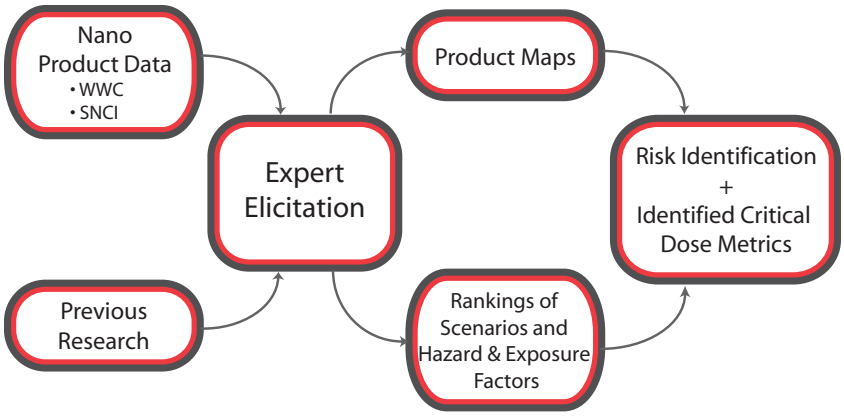
Figure 1

Methodology Diagram

Methodology used in this study shows initial data to interviews to risk identification. Two kinds of information were collected from the recorded expert elicitations: (1) product maps that capture connections and detail, and (2) rankings of scenarios and hazard and exposure factors, which summarize and rank key information.

WWC=Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies (www.nanotechproject.org).

SNCI=Silver Nanotechnology Commercial Inventory (www.nanotechproject.org/inventories/silver/).



The "why" behind a judgment or opinion is important as well as the professional background of that individual. This qualitative information is highlighted and integrated with quantitative data in the method outlined in this paper. (See the section below on The Product Map.)

It is not assumed that all of the information gathered by our method is heterogeneous (as they assumed in the Minnesota study).[19] Some sources of information are more reliable than others, and certain experts might have more experience on different factors. Weighting factors were not incorporated into the expert elicitation ranking method based on expert background. However, in the final analysis of each factor, relevant expertise was stated and the experts' specific comments were given along with rationale. Weighting experts is an approach that should be considered in future studies.

The goal of our research is to identify issues surrounding an emergent technology and to put those issues in context, so that risk identification can be performed more accurately. Eventually, these exposure scenarios, as well as hazard and exposure factors, can be assessed in the context of the regulatory system. Knowledge gaps and areas of high risk can help identify where there are research and oversight needs, facilitating anticipatory governance.

Our previous research used expert elicitation to identify risk, covering a wide range of manufactured nanomaterials.[20] This included products such as TiO2 sunscreens, colloidal silver toothpaste, carbon nanotube tennis racket, and fullerene-based MRI contrast agents. As of 2008, nanosilver continues to be the most prevalent use of nanomaterials on the consumer market, according to the Project on Emerging Nanotechnology Consumer Inventory (www.nanotechproject.org/inventories/consumer).[21] For this reason, silver nanotechnology was chosen as a case study for this project.

Table I

Expert Experience and Education

Ten experts were interviewed in this study. The lists above show the experts listed by experience and then by education. Because the identity of the experts is confidential, the order on these two lists does not correspond.

Experience

Government
- U.S. Environmental Protection Agency (U.S. EPA) Office of Pesticides

Industry
- photography industry

Non-Profit
- monitor regulation of pesticides

Academia
- crystallography, mineralogy, geochemistry, biogeochemistry
- biological and chemical oceanography, biogeochemical cycling
- aquatic toxicology of silver and various silver compounds
- acute and chronic mechanism of toxicology of silver in fish
- water purification using colloidal silver
- vascular cell biology, with an interest in nanopatterned and nanostructured surfaces
- surface modification of polymers and metals at the nano level

Education
- Bioengineering
- Biologist (2 experts)
- Chemistry, polymer chemistry and biomaterials
- Civil and environmental engineering
- Earth science, geological and environmental sciences
- Toxicology
- Fish physiologist and toxicologist
- Molecular eco-toxicologist
- Neurotoxicology, metal and heavy metal toxicology
- Training not given

Methodology

Two pools of information were created from the interview process (Figure 1). The first pool was product maps, which are information-rich and type-specific lifecycles that capture the detail from each successive interview. This detail includes exposure pathways and decision factors. The second pool of data contains estimated rankings of exposure scenarios and hazard and exposure factors coded from the interviews. This ranking process divides the scenarios and hazard and exposure factors into a hierarchy of importance. Put together, this results in risk identification of critical exposure pathways and identified critical dose metrics in the context of a much larger picture. This particular method allows for risk identification of silver nanotechnology through the adaptation of an earlier method used to compare various nanotechnologies and their applications.[22]

The Experts and Interviews

A list of 22 experts was compiled through literature searches and references through the Woodrow Wilson International Center for Scholars.[23] Each person was approached through email and phone for participation in the elicitation process. In addition to a letter of inquiry, information was provided on the interview format and on specific silver nanotechnology products as derived from the University of Virginia's Silver Nanotechnology Commercial Inventory (SNCI; www.nanotechproject.org/inventories/silver), along with examples of exposure scenarios and hazard and exposure factors. These hazard- or exposure-related factors are key in evaluating the technology and were derived from the interviews.[24]

Follow-up calls were made in cases in which the initial email request went unanswered. Five of the twelve experts who did not participate could not be reached. The remaining seven indicated that their expertise was not appropriate for this study. Table 1 lists the areas of expertise and education of the 10 experts who participated in this study.

The interview method used in this study complements expert elicitation studies in which large numbers of experts are asked to provide ratings of hazards. Multiple expert ratings provide a sense of whether there is a consensus among experts, and variance around the mean gives a quantitative indicator of reliability. However, sampling a large number of experts does not always guarantee accurate results when interpreting quantitative rankings. Opinions can be based on knowledge from a small body of research, which might be flawed.[25]

Detailed interviews of a few experts provide insight into the reasoning behind each expert's judgments, and also allow them to refuse to make judgments when they feel they are not qualified. This is why in this method the total number of experts is not as important as the breadth of experience of the small number of experts. Rankings and the reasoning behind them can be put into a context. This method also gives the interviewer the opportunity to become an interactional expert in nanotechnology risk assessment.

The Product Map

Figure 2 shows each of the components that make up our product maps. Each expert was engaged in a discussion to help identify and rank points of interest, such as exposure scenarios and life-cycle stages. They also helped identify exposure pathways and critical decision factors such as hazard and exposure factors that connect those points of interest, represented by lines. A third layer of detail was captured from the interviews, by connecting specific questions or thoughts of the expert to different parts of the map. This third layer or dimension can include the knowledge and oversight gaps addressed in the interview.

Each interview helped deepen the interactional expert's (interviewer's) understanding of silver nanotechnology by focusing on the experts' area of expertise in the context of silver nanotechnology products and exposure scenarios.

This expert elicitation method can be thought of as an iterative process. The figure below illustrates how different experts help create a complex picture of the system in question. As the interactional expert moves from one expert to another, a 3-dimension map is created. New points of interests are identified along with exposure pathways and decision factors. The 3rd dimension is not illustrated in this diagram.

In Figure 3, a) represents the information provided to the expert in the packet, an example of a nanosilver product type (such as solid) and the resulting general exposure scenarios (such as integration into a commercial product to use in manufacturing eventually ending in a landfill). In b), Expert 1 introduces new points of interests and exposure pathways. They might suggest other points of exposure along the product's life cycle. While each interview follows the same format, the interactional expert integrates the information from each previous interview into the next interview. Therefore, Experts 2 and 3, as illustrated in

Figure 2

Key Elements of the Product Map

The three elements of the product map are displayed. 1D represents the first dimension that is points of interest such as specific scenarios or destinations along a products life. 2D represents a second dimension that connects points of interest together. Here, decision factors are introduced that determine the fate and transport of silver nanoparticles. 3D captures the detail that does not fall into the first two dimensions. This includes knowledge gaps, new questions, and regulatory issues.

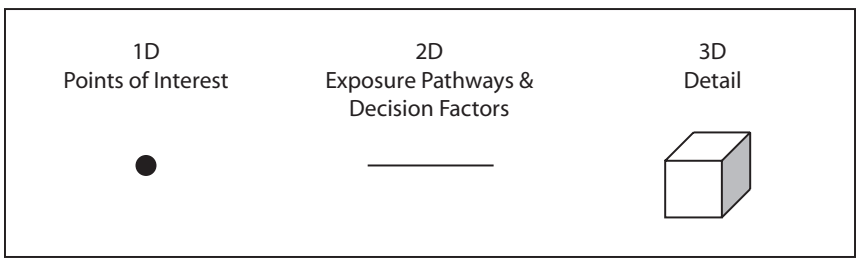
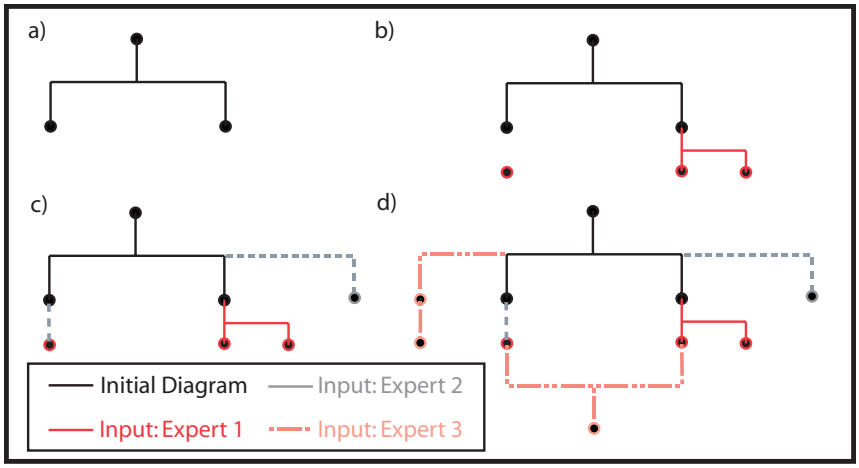


Figure 3

Product Map Evolution through Expert Elicitation

The iterative process of expert elicitation is displayed above. From a) to d) each expert adds new information and branches to the product map. This shows the types of complexity and richness that can be captured through this method.



c) and d), can build on or debate the relevant information collected from the previous experts. Depending on the expert, they may be better at adding points of interest (such as different exposure scenarios), or they might be better at adding decision factors based on their professional experience.

Product Map Example: Colloidal Silver in Clothing

To illustrate the information flow for this method of expert elicitation, one branch of the colloidal silver product class is shown in Figure 4. Other product classes or types were considered during the elicitation process but are not shown here. This example is pertinent because according to the SNCI, colloidal silver is the second most prevalent use of silver nanotechnology in commercial products and according to the experts in this study, colloids used in products such as clothing present the highest risk in terms of exposure and toxicity. Here we will focus on the use of nanosilver in liquid colloidal applications. A common use of colloids is in clothing. Colloid can be integrated directly into the fabric polymer or the fabric can be dipped in a colloidal silver solution. It can be assumed that there will be end-of-life-cycle points of interest such as discharge of silver nanoparticles to fresh water (which is of high concern to some nonprofit groups) and disposal of products containing silver nanoparticles in landfills.

Only the first two levels of the product map are displayed below (Figure 4). Details, such as oversight and knowledge gaps, are usually offshoots of particular decision pathways or points of interest. This could be demonstrated by adding detail of a knowledge gaps to a decision pathway. For example, geochemical cycling could be dependent on several factors such as water chemistry, aggregation/agglomeration characteristics, ion release and catalytic action, all of which are currently unknown. The difficulty in visual representation arises where factors start to connect between product maps, other exposure scenarios, and hazard and exposure factors. For instance, silver in solution or in sediment resulting from clothing could lead to other exposure scenarios such as ingestion or chronic exposure in aquatic organisms. Other types of colloidal silver exposure resulting from the use of detergents or cosmetics might follow similar routes of exposure. This almost requires that a new graphical interface be constructed to display the complexity of relationships between these factors. This is an area that should be investigated in future work.

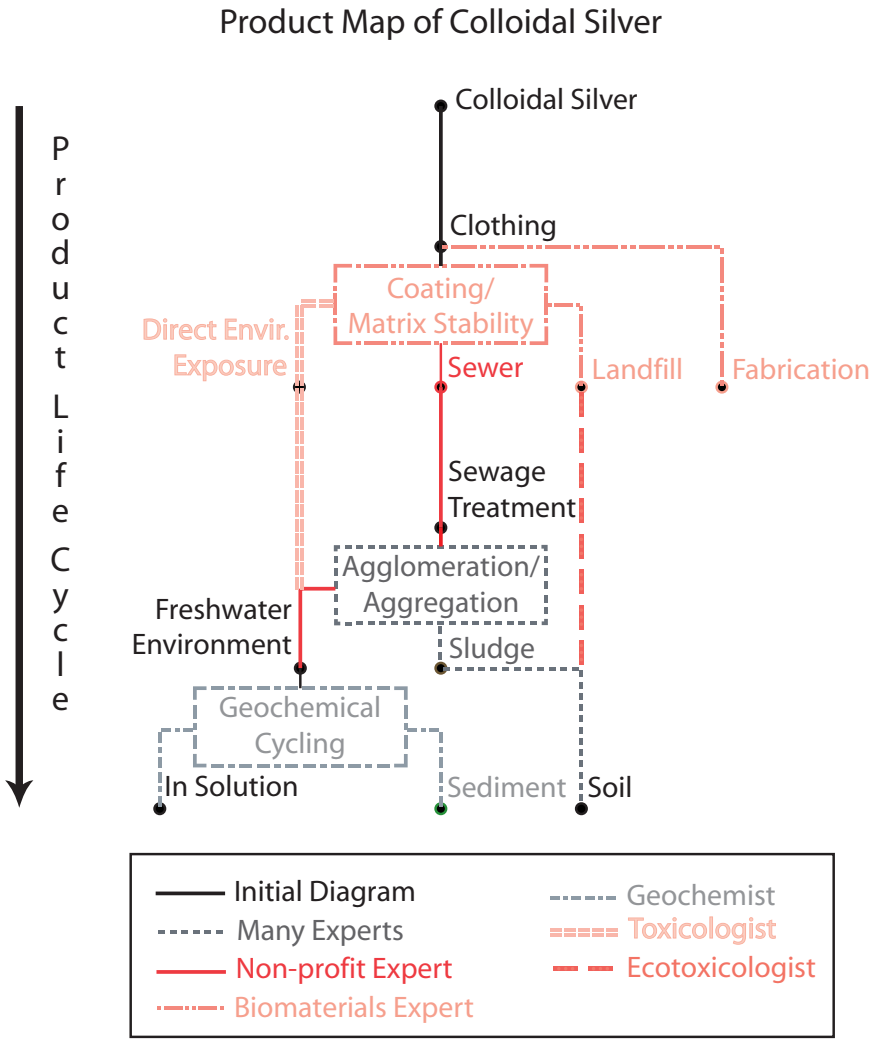
Starting with the non-profit expert, he pointed out that due to the regular washing of the clothes, there would be exposure to the sewer. This means that the nanosilver could end up in the fresh water environment, causing problems for aquatic life. Next the biomaterials expert identified exposure that could result from fabrication of the product. He also identified the decision factor — matrix stability — that would determine if the nanosilver on the fabric would end up in the sewer or landfill. Many of the experts agreed that whether the majority of nanosilver from the sewer would end up in the freshwater environment would depend on the hazard and exposure factors, as well as the agglomeration and aggregation characteristics of the nanoparticles. If the particles have a tendency to be taken up or become larger, then the majority of silver would end up in sludge, which is incinerated or used as fertilizer on crops. If not, then it would end up in the freshwater environment. While many of the experts felt the particles would agglomerate, what will happen to the various types of silver nanoparticles is still uncertain.

A geochemist with experience studying naturally occurring nanoparticles in the environment stressed the importance of understanding the geochemical cycling of the silver nanoparticles. This would help determine the eventual fate of these particles in the natural environment. Will they end up staying in suspension, moving out to sea, or being entrained in the

Figure 4

Excerpt from Product Map of Nanosilver

This shows 1D and 2D elements for one of the branches — clothing — of the product map for colloidal silver. Moving from top to bottom, the product lifecycle is displayed, from production to final destination. The color coding shows the progression of information added from different experts. Black text shows the points of interest derived from product information and previous research.



sediment? Knowledge of fate processes, in turn, will help determine which forms of aquatic life will receive the most exposure and under what conditions those types of exposures will occur.

A toxicologist mentioned that there could also be direct exposure in cases where the silver is released directly into the fresh water environment. He also talked about how silver ion release rates would determine the toxicity of these particles in fresh water. An ecotoxicologist connected leachate from a landfill resulting in more soil and ground water exposure. But for most experts, the issue of soil exposure was of little concern.

Rankings of Exposure Scenarios and Hazard & Exposure Factors

After initial analysis of the interviews and the creation of product maps, the interactional expert with the help of a research assistant, derived a list of exposure scenarios and hazard and exposure factors (shown in Table 1). The interview transcripts were coded; each scenario and factor was given a numerical ranking on a scale from high to low risk of exposure or hazard. These rankings were inferred from the opinions provided by the experts.

Figure 5 provides a diagram that summarizes the quantitative results from the 10 interviews. Due to the small sample size of experts, numerical averages were not provided. Scenarios and factors are presented in relation to one another. Large font and warm colors represents the scenarios and factors that received the highest rankings. These were the scenarios and factors that the experts pointed out as areas of high risk.

The order from top to bottom of each list represents the number of experts that commented on that particular scenario or hazard and exposure factors. Uncertainty of the experts was accounted for in the coding process; if an expert did not talk about that particular scenario or factor, he or she was not included in the ranking of that scenario or factor. In this way, only experts who had an expert opinion on that topic contributed to the ranking of that scenario or factor. For example, aquatic release was ranked as having the highest risk of exposure (along with chronic exposure) and because it is at the top of the list, it had the most experts that discussed that particular scenario. Dermal absorption, however, was mentioned by the least number of experts, but is third in the list of high-risk of exposure scenarios. By following each product map, these different exposure scenarios can be observed. Only the details for

colloidal silver in clothing are presented above (see Figure 4).

Note that Table 1 shows more hazard and exposure factors than identified in Figure 5, where only the hazard-related factors related to material toxicity are discussed. More factors related to exposure, material properties, and material reactivity were not included due to limited information provide by the experts. The experts were not comfortable with committing to a judgment on these factors, due to their lack of expertise in these areas. In those cases, discussed issues and knowledge gaps were recorded in the 3D detail level of the product maps.

Risk Identification

The combination of the product information, product maps, and the ranked exposure scenarios and hazard and exposure factors provides the necessary tools to perform risk identification. By looking at the product map, critical metrics that are essential for understanding silver nanotechnology and knowledge gaps can be identified. In the example of the product map for colloidal silver in clothing (see Figure 4), it can be seen that by better investigating and evaluating the exposure-related factors such as matrix/coating stability, it can be determined what area (direct environmental exposure, sewer or landfill) will result in the greatest silver nanoparticle exposure. This type of analysis where exposure and hazard-related factors are identified in the context of particular scenarios can lead to clear research-oriented goals and management issues.

Coding the interviews also provides another key source of information. This step adds a layer of scientific scrutiny to the information that experts provide during their interview. By coding the interviews, data are extracted in an objective manner that allows us to say with confidence under what circumstances the panel of experts believed there will be either a high risk of exposure or hazard.

While there were product maps created for several of the silver nanotechnology product types, it was clear from both the detail of the product maps and the inferred rankings that colloidal silver exposure to freshwater environments caused the greatest concern among the experts. Chronic exposure was a close second concern.

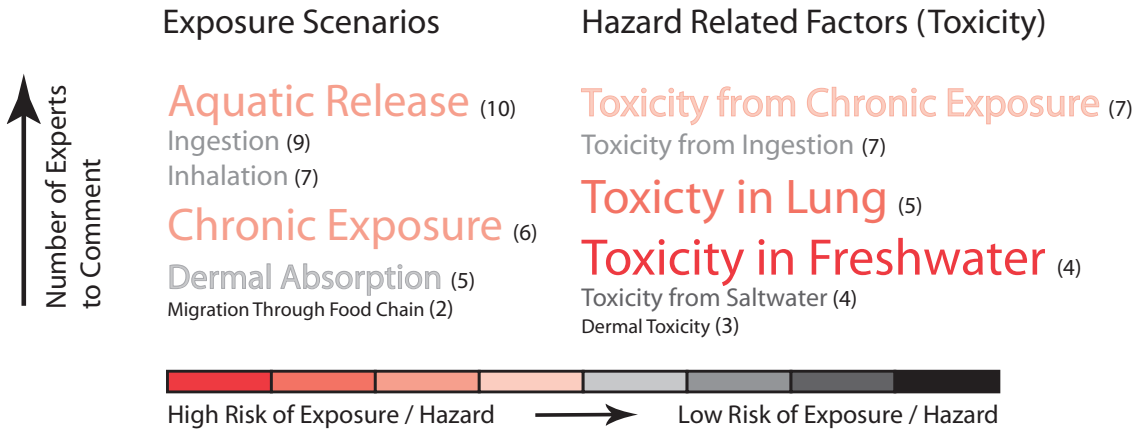
Expert Elicitation and Anticipatory Governance

Expert elicitation interviews can be a powerful tool for identifying gaps in research that are relevant to policy, especially if experts with policy experience are included, as they were in our sample. Identified high-risk scenarios can then be mapped against the current regulatory system to see where gaps occur. The two major oversight gaps identified in this study were a gap in the regulation of individual products that incorporate nanosilver, and the lack of an over-arching regulatory approach to deal with the compounding effects of hundreds of products.

Figure 5

Sample of Quantitative Results from Expert Elicitation Ranking: Exposure Scenarios and Hazard Related Factors, Material Toxicity[26]

Low to high risk of exposure and hazard is displayed by color and size on a scale from 1 to 5. Large and warm colored text is ranked high, while small and cool colored text is ranked low. Rankings were determined by averaging the scores from the total number of experts who commented on that particular scenario or factors. The number of experts who commented on each scenario and factors are displayed in black parentheses. Scenarios and factors are listed in order of most-talked-about scenario and factors to the least.



The majority of nanosilver products use silver because of silver's antibacterial properties. Antibacterials, which are a form of pesticide, fall under the regulation of the EPA's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (http://www.epa.gov/oecaagct/lfra.html).[27] There is an important distinction when talking about products that contain pesticides: only products providing antibacterial protection that make a claim of being antibacterial must be regulated under that statute. This is a loophole that many companies are using to avoid registering their products. Pesticides used to "protect" a product, not provide antibacterial benefit through use and "devices," do not have to be regulated through FIFRA. In September 2007 the EPA clarified its stance on ion-generating products such as the Samsung washing machine that is designed to kill bacteria on clothing by releasing silver ions. It stated, "A product that uses only physical or mechanical means to trap, destroy, repel, or mitigate a pest (including microbial pests) is a device and is not required to be registered (though its production and labeling are regulated). However, if the product incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate pests, then it is considered to be a pesticide and is required to be registered."[28] This should place many of the products currently on the market under the regulations pertaining to FIFRA if an antibacterial claim is made. However, very few if any of these products have been registered.

In May 2008, the International Center for Technology Assessment (ICTA) and a coalition of consumer, health, and environmental groups submitted a legal petition to the EPA demanding that EPA stop the sale of 260 potentially dangerous nano-silver products. They cited the hazard of bulk silver to the environment and the unknown effects of nanosilver on both human health and the environment. Some of their major concerns were with the pervasive use of antibacterials that will spur the emergence of resistant strains of bacteria, as well as the ability of nanosilver to adversely effect beneficial bacteria populations in wastewater treatment plants. One important factor they would like the EPA to deal with is "to clarify that nano-pesticides, such as nano-silver products, are new pesticide substances that require new pesticide registrations, with nano-specific toxicity data requirements, testing and risk assessments. Nano-silver must be classified as a separate substance than macro-silver based on the nanomaterial's capacity for fundamentally unique and different properties and because nanosilver has many new antimicrobial uses that are not previously registered as silver uses."[29] This is an important distinction because, as of now, nanosilver is regulated in the same way as bulk silver. Testing for EPA pesticide registration depends a lot on the uses of that product. If a company made a product that would end up in bodies of water, toxicology studies on aquatic organisms would be required during the registration process. The EPA bases the testing of a substance on the most toxic form of that substance. For the case of silver, silver ion is considered the most hazardous form. The current levels of silver in the regulations are based on tests done with silver nitrate, which easily dissociates into silver ions when placed in water.

In response to CTA and the political climate surrounding nanotechnology, the EPA responded on November 19, 2008 with a "Petition for Rulemaking Requesting EPA Regulate Nanoscale PRoducs as Pesticides." They sought comments on a petititon request that "the Agency classify nanoscale silver as a pesticide, require formal pesticide registration of all products containing nanoscale silver, analyze the potential human health and environmental risks of nanoscale silver, take regulatory actions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) against existing products that contain nanoscale silver, and take other regulatory actions under FIFRA as appropriate for nanoscale silver products."[30]

Our expert elicitation and research suggests that there are unique risks associated with nanosilver that justify the concerns of the CTA. One of our experts noted that "silver nanoparticles are highly reactive due to their size, compared to bulk silver." This means they would lead to increased production of silver ions, and also catalyze the formation of oxygen radicals, potentially varying under different water conditions. But these antibacterial mechanisms are poorly understood. In our current research, we are studying these mechanisms and their effect on bacteria. It is clear that one cannot use the mass-based regulations for a material that has an increase or decrease in toxicity under various water conditions. This is especially important when addressing the topic of the regulation of silver nanoparticles.

While each use of nanosilver produces its own challenges, the total effect of using nanosilver in products ranging from toothpaste and home disinfectant to industrial food applications and food packaging is not being monitored. As far as regulatory oversight goes, much of it is based on point-source contamination, such as monitoring the effluent of a processing plant or individual product development. One expert commented on the potential danger of chronic exposure to nanosilver, "You should not buy them, it is the worst use of antibiotics. It is low level chronic use…[and] creates resistance all over your house." The creation of resistant bacteria was only one of many concerns that the experts raised with the extensive use of nanosil-

ver in commercial products. Not only can this expert elicitation method help to identify regulatory gaps both within the current legal system and governmental oversight, but it shows the context in which those gaps exist, illustrated with pertinent examples and scenarios.

Next Steps

It is important to note that risk identification methods such as this in the context of anticipatory governance are meant to be part of a larger effort to manage emergent technologies. Identifying the risk is the first critical part of risk analysis. The following steps should include but not be limited to taking what was learned in the risk-identification stage and applying it. This will involve laboratory and field studies of high-risk exposure scenarios and hazard- and exposure-related factors identified by the experts. Transparent, widely disseminated results can be used to improve oversight. Results can also be fed back into future expert elicitation. This kind of iterative process is exactly what is required for adaptive management.

In this next stage of research, we are taking what we learned and taking questions derived from the product map and rankings to the lab. Aquatic exposure and fresh water toxicity were identified as areas of high risk of exposure and hazard. In the interviews an obvious knowledge gap emerged in estimating actual exposure amounts. While experts were comfortable talking about exposure pathways and factors that either increased risk of exposure or hazard, they were not willing to commit to an opinion on how much exposure was going to occur.

In seeking an opportunity to investigate aquatic exposure scenarios, we began a collaboration with a group in the University of Virginia's Environmental Engineering Department. Our focus is on investigating aquatic release exposure scenarios of silver nanoparticles through the use of colloidal silver on ceramic filters used in water filtration. This is an example of a potentially beneficial aquatic application of silver nanotechnology. This scenario also touches on many of the questions brought up in the product map for colloidal silver, such as investigating ion release rates, aggregation characteristics, and matrix/coating stability. We will specifically focus on the kinetics of silver ion and reactive oxygen species release from the particles under different water conditions, as well as silver ion's effects on bacteria.

Conclusions

Nanoparticles are included in the first generation of nanotechnology — nanomaterials.[31] Overall, the U.S. regulatory system is likely to be much better adapted to nanoparticles than to more complex nanotechnologies that purposefully interact with their environment. In the nanoparticle phase, we have an opportunity to develop methods and capabilities that can be extended to more complex nano-products and nano-systems. Expert elicitation is one of these methods. This method should include detailed interviews in which the experts explore issues, provide reasons, and indicate where they are and are not comfortable making judgments. This expert elicitation, along with laboratory research and consultation with stakeholders, can be used to facilitate adaptive management of emerging nanotechnologies. One additional step would be to bring experts who participated in an elicitation together with each other and with additional stakeholders to talk about the regulatory implications, especially in the light of new research conducted to address knowledge gaps identified in the elicitation. This may be work that could be carried out by the new National Science Foundation Centers for Environmental Implications of Nanotechnology at Duke University and UCLA, or by the Project on Emerging Nanotechnologies in Washington, D.C. Such trading zones can serve as a mechanism for anticipatory oversight and governance.

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