Risk Identification in the Life Cycle of Nano-Products

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ABSTRACT

The marketplace for products based on nanotechnology (nano-products) is poised to grow tremendously. However, in order to realize the projected market potential of nanotechnology, the uncertainties posed during the nano-product lifecycle need to be characterized through the upstream identification of risks and opportunities arising from the use and disposal of nano-products. We present here, a methodology to identify the degree and types of risks from nano-products using a scenario analysis approach that allows for expert elicitation on a set of pre-identified exposure "scenarios" and risk "triggers" to obtain relative scores on the likelihood of occurrence of the exposure scenarios, their hazards, and the particular nano-product properties that trigger the risk. Through such a framework our vision is to identify which products pose greater risks, where these risks are in the product life cycle and how the society is impacted due to these environmental risks. Significant intersections of the high-risk scenarios with the high-risk triggers include the accentuation of impacts from air release and water entrainment due to easy bioavailability, impacts on health and environment due to exposure to antibacterial nanoparticles outside of the product application cycle, and the effects of ease of dispersion of nanoparticles on susceptible populations. Since this framework carries out risk identification in conjunction with regulatory gaps, we anticipate that it will be useful in developing approaches to the risk-based regulation of nanotechnology, rather than the list-based approaches that are currently being used.

Keywords: nanomaterials, risk, consumer products, scenario analysis, expert elicitation.

1 INTRODUCTION

While some applications of novel nanostructures are still in an early research stage, other nanotechnology applications have now moved beyond scientific journals into the marketplace. On one hand are products that replace bulk ingredients with nanoscale counterparts such as improved sunscreens (nanoscale titanium dioxide instead of bulk titanium dioxide) or stain-resistant fabrics; and on the other hand are products enabled through novel nanoscale phenomena, such as field emission properties of carbon nanotubes for ultra-light flat panel displays in cell phones [1] or quantum-dot based lighting. Spurred in part by worldwide investment in nanotechnology of a few billion dollars per year [2], an array of hundreds of nanotechnology-enabled products [1] is available in the US alone with projected worldwide revenues of $150 billion by 2008 and $3 trillion by 2014. The nano-product marketplace is expected to grow tremendously. In this context, early-stage identification of environmental impacts and risks from nano-products is vital to their large-scale acceptance by society, and this requires studies in identifying real risks versus those unsubstantiated by scientific data. Prior attempts at formal environmental risk assessment have been stymied by a paucity of toxicological data [3, 4] thereby greatly hampering the field of risk perception and its communication to the general public [5]. There is hence a need for frameworks that allow for the upstream analysis of the risks and opportunities that nanotechnology presents.

We present a framework that uses novel nanomaterial properties and traditional risk assessment methodologies to identify risks from nanotechnology-enabled products in the marketplace, hence called "nano-products".

2 CHALLENGES TO RISK ASSESSMENT OF NANOTECHNOLOGY

Risk is defined as a measure of probability and severity of adverse effects [6]. It follows that risk must be measured as a function of likelihood and severity of the effect. The functional definition is: risk = f(hazard, exposure). Risk assessment methods use quantitative predictions of health impacts and thus do not attempt to estimate risk with absolute certainty. Most risk assessments methodologies employ models that can be fit to the system under study. These mathematical models themselves come with a set of their own uncertainties due to model parameters, parametric uncertainty, and due to unclear or unidentified relationships between model variables, model uncertainty [7]. The aim of risk assessment is not to arrive at a single risk or adverse effect but to allow a range of possible consequences.

Identification of risks from nanotechnology is already a topic of much interest to industry and academia [5]. Why is an upstream analysis particularly important for nanotechnology? The answer is related to the degree of uncertainty it poses during its lifecycle: synthesis, use, and disposal cycles. A few of these uncertainties are related to science and technology issues, for instance, the hazards posed by nanomaterials within an EHS (Environmental, Health and Safety) framework. Others are related to how they fit within the regulatory system. Regulatory systems usually tend to react to known risks, hence, the rapid

development of new technologies like nanotechnology pose a special set of problems. We also need, as a society, tools for identifying potential impacts as technologies emerge, so at the very least data can be collected and system impacts monitored. Such analysis can be fed into design for the environment programs for emerging technologies.

3 METHODOLOGY

Our method for identifying potential risks of emerging technologies was to consult experts at the cutting-edge of EHS research about hazards and work with them to develop exposure scenarios and risk triggers. We used a panel of ten internal experts (those who we have collaborated with) and ten external experts from the areas of chemistry, materials science, toxicity, environmental sciences, and technology policy areas. The overall methodology of the framework follows in four phases: scenario analysis, expert elicitation, multi-criteria analysis, and risk identification and mapping.

3.1 Scenario Analysis

We started with a set of nano-products available in the marketplace and obtained complete information about the product composition and use [1]. The products were the following: air freshener, battery, food supplement, field emission display, MRI contrast, sunscreen, tennis racquet, and toothpaste. The products were classified into five classes of nanoparticles: metals, metal-oxides (ceramics), carbon nanotubes, fullerenes, and semiconductor quantum dots. The applications may be classified as passive nanostructures where material properties are not actively modulated, such as sunscreens or disinfectants, or active nanostructures where one or more of the nano-enabled properties can be actively turned "ON" and "OFF" in a seamless manner. For example, metallo-fullerenes for imaging and targeted delivery or quantum-dot based lighting.

Next, based on previous research and literature reviews, our methodology was to develop scenarios and questions for expert elicitation. These questions were continuously refined based on preliminary interviews. The scenarios were broken down into three categories: exposure scenarios, risk triggers, and regulatory gaps. These risks can also be mapped along the regulatory life cycle of a particular nanotechnology-based product [8]. All the scenarios through which human health or the environment may be impacted by the nanoparticles in the products during their use and disposal were then considered as exposure scenarios.

Due to nanoparticles characteristics that differ radically from their bulk counterparts, certain properties within the nano-product lifecycle can trigger a higher risk potential. The particular nanomaterial properties that make them different from bulk counterparts are called triggers for risk. Properties that enable the nanomaterial to be freely available to a larger population are grouped under exposure-related triggers and those properties that cause the nanomaterial to be potentially harmful to human health or the environment are grouped under hazard-related triggers. In this manner we can attribute particular risks and risk triggers to particular nano-products. Finally, the effect of regulatory gaps and knowledge gaps on the identification of risk also needs to be considered.

	Exposure Scenario	Description
Use	Inhalation	Inhalation of nanoparticles in the product during use
	Skin absorption	Absorption of the nanoparticles into skin
	Ingestion	Accidental ingestion of nanoparticles in the product during use
	Water Entrainment	Entrainment of nanoparticles in water system or the sewer during product use
	Air Release	Release of nanoparticles in the air during product use
Disposal	Inhalation	Inhalation of nanoparticles in the product when it is disposed
	Skin absorption	Absorption of the nanoparticles into skin
	Ingestion	Accidental ingestion of nanoparticles in the product during disposal
	Water Entrainment	Entrainment of nanoparticles in water system or the sewer during product disposal
	Air Release	Release of nanoparticles in the air during product disposal

Table 1. Exposure Scenarios for Expert Elicitation

3.2 Expert Elicitation

In risk assessment situations where information is lacking, expert elicitation is often used to fill the gaps [9-12]. Using the set of described triggers, experts were drawn into discussions on the relative importance of the triggers and how they may apply to particular nano-products. The likelihood of scenarios, including bounds and range of values of important parameters within the scenario were assessed. The discussion included exposure scenarios and risk triggers, those that accentuate or mitigate risks. In the future, this will aim to include regulatory gaps, knowledge gaps, and perceptive risks [13] (those perceived as risks by the larger society) in future work. A cross-section of experts from the government, industry and the academia were included. A survey was sent out to them with the product information, the triggers and the scenarios for each product. In the ensuing discussion, they weighed each trigger from 1 to 5 for each nano-product based on the degree to which the property was displayed within the

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particular nano-product in its life cycle. Next, they rated each exposure scenario as high (H), medium (M) or low (L) based on their evaluation of the likelihood of the scenario and its impact on human health and the environment. Once scores were given for the exposure scenarios and risk triggers, multi-criteria analysis was used to determine the risk score or risk profile of the material in the product.

Exposure-Related Triggers
Nanomaterial Only: Does the material exist only in the nano form?
Coating Stability: Are there scenarios where the coating breaks?
Media-Dependent Property: Does the material behave differently in different medias?
Free Nanoparticle: Would there be scenarios where the nanoparticles could be freely available within the product lifecycle?
Other Products: Is the nanomaterial used in different products?
Multiple Disposal Pathways: Is the product disposed in different ways, each with a different degree of effect on the environment? Recycling would have the least effect.
Particle Size: Is the particle size less than 200 nanometers?
Dispersibility: Does the material disintegrate into free nanoparticles in water?
Hazard-Related Triggers
High Aspect Ratio: Does the material resemble a fiber, like asbestos?
New Product: Is the product itself a new nano-application or is the nanomaterial used only for performance enhancement?
Free Radical Generation: Do the nanoparticles in the product generate free radicals in the presence of sunlight?
Susceptible Population: Are there scenarios during the product use where significant number of people would be more susceptible to have a higher degree of effects?
Antibacterial Properties: Does the nanomaterial kill/harm useful bacteria in the environment or the human body?

Table 2. Risk Triggers for Expert Elicitation

3.3 Multi-Criteria Analysis for Scoring of Exposure Scenarios and Risk Triggers

After the survey responses were collected from experts, the nano-products were scored in the following categories: exposure scenarios and risk triggers. The exposure scenario scores were obtained from the responses to those describe in scenario analysis. This process provided us with a hazard rating and an exposure rating for every scenario for each product.

From expert responses, scorers were assigned to each product were added to determine the final weighted score in hazard- and exposure-related triggers separately. The higher the hazard and exposure related scores, the higher is the potential hazard from the nanomaterial present in the product and higher the chance of environmental and human exposure to the material.

3.4 Risk Identification and Mapping

From the expert responses, we can compare the scores assigned to each risk trigger within a product to analyze how particular nanomaterial properties caused the product to impact human health and the environment. Also, the results from the multi-criteria analysis can be used to highlight all those scenarios that fall under 'H' and 'M' rating as potentially high-risk exposure scenarios. Triggers that have relatively higher weight than others can be classified as potentially high-risk triggers. In some cases, high-risk triggers and high-risk exposure scenarios cascade to cause even greater concern than either alone. These high-risk triggers and scenarios were the high-risk hot spots for future research and possible regulation. In the terminology of statistics, these independently scored risk trigger and exposure scenarios can cause interaction effects for risk identification.

4 CONCLUSIONS

There were eight nano-products considered in this study. From a preliminary analysis of expert responses to the survey of exposure scenarios and risk triggers, there were broad conclusions about these nano-products:

- Aerosolized nanoparticles pose a greater health hazard as compared with other types of nanoparticles in the products.
- Ingestion exposure is the highest for products, such as toothpaste and food supplements, that are used orally.
- For products in which the nanoparticles are bound in a matrix, such as tennis racquets, field emission displays, and batteries, the risk of human and environmental exposure is less.
- Hazard to the environment is the highest from nanoparticles that are easily bio-available.

- Products that claim to have antibacterial properties caused the greatest environmental concern to the experts across the board.

For risk triggers, each product is scored from 1 (low risk) to 5 (high risk). These products can be divided into three regions of high, medium and low potential risk from the products. High hazard-high exposure, high hazard-low exposure and low hazard-high exposure represent a high potential risk region, medium hazard-medium exposures represent medium potential risk and low hazard-low exposures represent low potential risk region. Preliminary analysis suggests that relative risks are higher for sunscreens, toothpastes, and air fresheners based on number and weights of both 'high hazard' and 'high exposure' scenarios. Food supplements and MRI contrast agents pose some significant scenarios for high-hazard, but few scenarios for high exposure. Field emission displays and racquets pose medium risk levels, and batteries pose the least risk level to human health and the environment. Products like sunscreens and air fresheners are high risk because the nanoparticles in these products can be disengaged from the matrix or composite to which they are bound. Nanoparticles within displays, racquets and batteries are bound on the other hand, but could become free during the disposal stage.

5 FUTURE WORK

This study seeks to present a methodology for the upstream analysis of risks from nanotechnology, and illustrate a preliminary set of results for air freshener sprays. The expert elicitation process is being continuously widened to consider more scenarios and risk triggers, and the next step is to include regulatory gaps and knowledge gaps in the process. As indicated earlier, nano-products are very likely to fall through regulatory gaps due to classification and nomenclature issues. In previous work we analyzed the nano-product life-cycle stages where particular regulatory agencies may be involved and possible regulatory gaps [8, 14, 15] can occur. In future work we will aim to assess which regulatory gaps apply to which nano-products, to what extent, and where in the product life cycle. This will establish pathways to move from the current regime of list-based regulation to risk-based regulation. In this context, risk is meant to characterize the ability of regulations to affect the marketing and production of nanotechnology-based consumer products. Future work will focus on how the regulations could apply by assigning weights to each regulation for every product.

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