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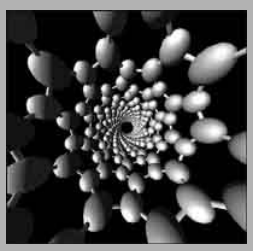

Analyzing the European Approach to Nanotechnology

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Introduction

Three reports have recently emerged from different European countries that attempt to detail, analyze, and assess the potential problems and benefits, pitfalls and possibilities, and known and unknown issues related to developments in nanoscience and nanotechnology. These different surveys and overviews—"Nanotechnology: Small Matter, Many Unknowns," produced by the Swiss Reinsurance Company (heretofore known as Swiss Re), "Nanoscience and Nanotechnology: Opportunities and Uncertainties," produced by The Royal Society and the Royal Academy of Engineering in Great Britain, and "Industrial Application of Nanomaterials: Chances and Risks," produced by the Future Technologies Division of Technologiezentrum in Germany—reach similar conclusions as to the overall current state of risk analysis, regulatory framework, and public participation with regards to nanotechnology. In short, all three reports conclude that while little specific information is available as to the potential harms inherent in nanotechnology, there is reason to believe that, alongside the positive impact of these technologies, real, inherent dangers could arise that have negative environmental and personal health impacts.

In order to understand emerging thinking on these subjects, I have compared the findings of these three reports with respect to six different issues: health risk analysis, environmental risk analysis, worker health risk analysis, existing regulatory framework, presumed regulatory ethos, and public education. Upon initiating this comparative analysis, it was assumed that there would be some degree of cross-referencing between these three reports, particularly because they were prepared roughly at the same time and originated from roughly the same geographical area (Europe). However, there was little apparent influence between the three reports, thereby making their conclusions even stronger and more pressing, since they appear to have been developed mostly independently of one another, more in parallel than in connection. In addition, it should be noted that an additional, shorter report, released by the Health and Consumer Protection Directorate General of the European Commission as a workshop summary on nanotechnology risk analysis, was analyzed for comparisons and contrasts with the other three. Though not intended as a rigorous overview of the subject, this report's findings also reinforce the conclusions drawn below, particularly by re-emphasizing the need to

conduct further toxicology tests on nanoparticles and by calling for adoption of the precautionary principle as a guiding ideology when data on the health and environmental impacts of nanotechnology is lacking. It should also be noted that in order to highlight some of the major findings of the three main reports, I have taken the liberty of highlighting key quotations from each paper in bold and in italics. Hopefully, this step will make comparing the similarities and slight differences of each report clear and easily accessible to the reader. At the end, I have also condensed these findings into a single table to provide a more compact, side-by-side comparison of each report.

Health Risk Analysis

In their technical analysis of nanotechnology, all three reports concluded that nanoparticles may have undue negative health consequences for the heart, lungs, and brain if they are able to enter the body through skin contact, inhalation, or ingestion. Moreover, all three reports concluded that since not enough toxicological data detailing adverse human health effects have been conducted, the only current method to respond to such worries is by way of analogy with such materials such as asbestos and ultrafine particles. In particular, the Swiss report noted that it may be the case that "systematic defects only emerge over time" and may remain "undetected for a long time."[1] Therefore, they recommend that "***if the risks of nanotechnological products are to be assessable and manageable, tests to determine their long-term toxicity are advisable. New kinds of testing and experimental methods may be required***."[2]

Along these lines, the report of the Royal Society points out that "***few studies have been published on the effects of inhaling free manufactured nanoparticles and we have to rely mainly on analogies with results from studies on exposure to other small particles***."[3] To solve this problem, this report recommends that as new nanotechnology-based products come to market, "information on the toxicology of ingredients such as nanoparticles include a requirement for relevant data, and the methodologies used to obtain them, to be placed in the public domain."[4] Similarly, the German report notes that acceptable "hazard identification, hazard characterization, exposure assessment, and risk calculation…have not been investigated yet and are still unknown."[5] However, this report concludes that "***Most critical with regard to potential health and environmental risk are***

nanoparticles dispersed in air (aerosols), because of their mobility and the possible intake into the human body via the lungs with represents the most critical exposure route for humans."[6] To offset these possibilities, the German report recommends "development and standardization of a low-cost throughput *in vitro* assay for toxicological screening of nanoparticles."[7]

Environmental Risk Analysis

In addition to the problems that nanoparticles may pose when directly inhaled, ingested, or applied to the human body, the three reports also conclude that a more general environmental risk exists when such particles enter the soil, the water, or the air. The point is that while nanoparticles may be released into the environment to clean up existing contaminants, they may also serve to become a new kind of non-biodegradable pollutant that may also remain in the environment indefinitely. The Swiss report argues that in order "to assess the potential risk in terms of scale, one must be familiar with the dissemination routes of the potentially hazardous substance."[8] Understanding how these "dissemination routes" operate—whether they are through the conscious release of industrial waste or an accidental leak of unpurified, nanoparticle rich air—is key with respect to the environment, for the report concludes that "***the elimination of nanoparticles from the environment would be extremely difficult—a major challenge to the manufacturing industry***."[9]

The Royal Society report agrees with the above analysis, proclaiming that "***there is virtually no information available about the effect of nanoparticles on species other than humans or about how they behave in the air, water or soil, or about their ability to accumulate in the food chains***."[10] They recommend that "research into the hazards and exposure pathways of nanoparticles and nanotubes is required to reduce the many uncertainties related to their potential impacts on health, safety, and the environment," all of which should be undertaken by "an interdisciplinary centre" focusing on "the toxicity, epidemiology, persistence, and bioaccumulation of manufactured nanoparticles and nanotubes."[11] While the German report does not offer much additional insight into understanding the environmental effects of nanoparticles, they do agree that "***in view of the fact that data on exposure assessment are lacking, a full risk assessment of***

nanoparticulate materials in most cases is not feasible at present."[12] However this report does recommend the usage and employment of "hazard trigger algorithms" that will help rank and list "relevant factors," such as production volume, potential exposure, solubility, and particle diameter," to create a "first estimation of potential risks of nanomaterials/particles."[13]

Worker Health Risk Analysis

All three reports highlight worker safety as one of the most important issues in assessing the risks of nanotechnology, so important that this issue should be conceived of as a separate variable or category. Since factory workers interact with substances directly and continuously, their health and safety should be of paramount concern. In particular, all three reports point out that workers must be careful throughout the entire production process, from fabrication to transportation to storage. The Swiss report notes that workers must be especially careful "during loading and unloading of semi-finished or end-products at the production facility."[14] To offset these concerns, this report recommends that particle exposure limits be reduced to account for the potentially dangerous health impact of nanoparticles and that new worker safety devices, such as a "nano-compatible 'glove-box'" or nano-compatible respirators, need to be developed to avoid potential dangers.[15] The Royal Society report recommends that worker safety regulations be reviewed and that "lower occupational exposure levels" be set to avoid any unknown dangers.[16] In addition, this report recommends a review and updating of management procedures related to accidental workplace releases.

The German report devotes an extended section to worker safety and "best practices" in the work place. This report also concludes that "***contamination and exposure to workers is more likely to happen during handling and bagging of material and also during cleaning operations of the manufacturing equipment***."[17] This report asserts that "workers must receive training regarding the need for respirators as well their proper use," as well as recommending that "personal protective equipment" be used as "another means of isolating the worker from the potential exposure."[18] To sum up, the report concludes that "***at present no regulations exist which refer specifically to the***

production and application of nanomaterials or nanoparticles neither for worker and consumer safety nor for environmental protection."[19]

Regulatory Framework

Each of these reports concluded that in order to deal with the potential health and environmental risks of nanotechnology, a new and improved regulatory framework needed to be developed and implemented. Along these lines, each report criticized government regulatory agencies for not separating out nanoparticles as completely new kinds and classes of materials requiring special review and oversight. For instance, the Swiss report notes that "***Nanotechnologically manufactured products were not subject to any special legislation. There were neither special regulations, recommendations on how such products or their base materials were to be handled, nor any obligation to label such products for what they were***."[20] This report presented the clearest argument why a new nano-specific framework was needed: "There are sound reasons for placing nanoparticles in a class of their own. Nanoparticles can enter the body by other routes than those used by microparticles. They can penetrate parts of the body that are protected against larger particles and enter into the systematic circulation. They are also presumed to be more reactive, so that under certain circumstances, interactions harmful to health may ensue."[21] In addition, all three reports suggest that each government's regulatory process be in-line with accepted international standards. Along these lines, the Swiss report suggests that, in order to avoid regulatory disputes and misunderstandings between countries, "***it is essential to have an internationally valid standardization of nanotechnological substances and materials as well as a uniform nomenclature***."[22]

The Royal Society report devoted an entire, in-depth section to regulation. The report suggested that while "at present, regulatory frameworks at EU and UK levels are sufficiently broad and flexible to handle nanotechnologies at their current stage of development," it is necessary that "***chemicals produced in the form of nanoparticles and nanotubes be treated as new chemicals under these regulatory frameworks***."[23] In addition, the report recommended that the regulatory framework of national and regional governments should be updated regularly, if not annually, to take into account new toxicological evidence. Moreover, they called upon manufacturers to "publish details of

the methodologies they have used in assessing the safety of their products containing nanoparticles that demonstrate how they have taken into account that properties of nanoparticles may be different from larger forms."[24] Also, the report recommends that regulatory bodies "include future applications of nanotechnologies in their horizon-scanning programs to ensure that any regulatory gaps are identified at an appropriate stage."[25] In short, this report recommends that regulatory agencies be vigilant and constantly update their regulatory regimes to respond to new kinds of nanoparticles that are used in products entering the human body and the environment.

The technical nature of the German report does not lend itself to an extended discussion of regulation, yet it does agree that changes in product oversight need to be made. It concludes that "***a focus should be laid on adapting existing legislation to match the requirements for a safe industrial use of nanoparticles and nanomaterials***."[26] Moreover, along the lines of the Swiss report, the German report notes that "international standards (including a nomenclature for nanoparticles/nanomaterials) and guidelines" are necessary to ensure for successful scientific exchanges and inter-comparisons of experimental results.[27]

Regulatory Ethos

The recommendations for greater regulatory and legislative oversight put forth by each report emerged from a shared underlying notion of caution, care, and concern. Each report approached the issue of managing the risk of nanotechnology with the philosophy that, all else being equal, the danger of these technologies should be assumed real and present until proven false. Each report underscored the notion of encouraging scientific and technological innovation, yet they concluded that the potential risks could be so grave and undesirable that a more prudent approach is necessary.

Along these lines, the Swiss report summed up its findings with the claim that "***In view of the dangers to society that could arise out the establishment of nanotechnology, and given the uncertainty currently prevailing in scientific circles, the precautionary principle should be applied whatever the difficulties***."[28] In turn, the report proposes that the best way to ensure that these technologies are safe and effective is to reach a shared understanding of how these technologies will be reviewed and analyzed. The report

concludes that "***the main precondition for successful risk assessment in a technology as complex as nanotechnology is finding a consensus among industry representatives, legislators and research institutes concerned***."[29]

Similarly, the Royal Society report espouses this cautious approach by concluding that "***some regulations will need to be modified on a precautionary basis to reflect the fact that the toxicity of chemicals in the form of free nanoparticles and nanotubes cannot be predicted***."[30] Also, while the German report does not offer language as strong or as insistent as either of the other two reports, it does suggest that "the impact of these materials on worker safety, consumer protection, public health and the environment will have to be considered carefully by legislation and regulation authorities."[31]

Public Education

Both the Swiss and UK reports noted that the very novelty of nanotechnology provides manufacturers, policymakers, and researchers the opportunity to shape the broader public perception and understanding of these new developments. Unlike stem cell research, genetically modified food, and nuclear power, nanotechnology has yet to be perceived as a widespread, general public threat, so there is a window of opportunity that should allow all key stakeholders to present accurate, factual information on its potential benefits and harms.

The Swiss report notes that "***whether the public accepts the new technology and sees in it advantages for itself—or rejects it—will largely depend on how well informed it is and to what degree it is able to make objective judgment***."[32] For this reason, the Royal Society report recommends that funding be allocated to undertaking a "sustained and extensive program involving members of the general public and members of interested sections of society."[33] The German report also agrees that "***an open public dialog with citizens and consumers is absolutely necessary as a basis for an objective judgment on nanotechnology and to avoid baseless fears***."[34] By ensuring that the public at-large is well informed about issues surrounding nanotechnology, all stakeholders will be able to manage any problems and difficulties is a more open and transparent manner.

Conclusion

In conclusion, it is evident that these three reports share a similar worldview regarding the risks and regulatory responses for nanotechnology. Each, in its own way, made clear that not enough information exists as to the exact biological and environmental threats of nanoparticles. Research along these lines is paramount and of the utmost importance. Similarly, the overall regulatory framework, while continually adapting, has yet to fully comprehend the novel nature of these particles. Even the report from the European commission points out that the uniqueness of nanotechnology may lead to a host of potential regulatory responses, from adopting a "laisser-faire" attitude to relying on "voluntary measures" for guidance to launching a "comprehensive, in-depth regulatory process."[35] By claiming that the only way to effectively manage the potential risks of nanotechnology is to treat these particles as fully distinct entities subject to special rules and regulations, each of the reports explicitly questions whether it is possible to ensure for their safe handling under existing regulations. Open communication of these risks will be central in determining how the public will react to a nanotechnology mishap, so it behooves the industry as a whole to take steps toward creating a robust and flexible management infrastructure and toward making their precautionary approach evident from the start.

Issue	Swiss	UK	German
Health Risk Analysis	● Little data available ●Defects emerge over time ● Could damage lung, heart, and brain ● Analogy with asbestos used to inform regulatory framework	● Little data available ● Need new tests to understand toxicity ● Analogy with asbestos used to inform regulatory framework	● Most risky form is inhaling aerosol particles ● Could damage lung, heart, and brain
Environmental Risk Analysis	● Little data available ● Nanoparticles could remain in air, soil, or water	● Little data available ● Nanoparticles could remain in air, soil, or water	● Little data available
Worker Risk Analysis	● Reduce exposure limits ● Safety devices not robust ● Need "best" handling and transportation practices	● Reduce exposure limits ● Review accident management procedures	● Need worker training on protective measures ● Need "best" handling and transportation practices
Regulatory Framework	● Nanoparticles should be New Class of Materials ● Common international standards needed	● Nanoparticles should be new class of materials ● Continually adaptable and emerging regulatory framework ● Include provisions for future applications	● Regulatory approach needs to be adapted ● Common international standards needed
Regulatory Ethos	● Precautionary principle supported	● Cautious, though specifically states there is no need for a moratorium on production	● Careful consideration of hazards required
Public Education	● Window of time currently available to shape public perception ● Do not wait for negative event to shape public opinion	● Fund research into public attitudes ● Suggests bi-annual review of new nanotechnologies	● Communicate risks to public ● Initiate public dialogue including all stakeholders

About the Author

Evan Michelson received a B.A. in Philosophy of Science from Brown University, a M.A. in the Philosophical Foundations of Physics from Columbia University, and is currently pursuing a M.A. in International Science and Technology Policy in The Elliott School of International Affairs at The George Washington University.

Endnotes

[1] Annabelle Hett, "Nanotechnology: Small Matter, Many Unknowns," Swiss Reinsurance Company, Zurich, Switzerland, 43.
[2] Hett, 43.
[3] The Royal Society and The Royal Academy of Engineering, "Nanoscience and nanotechnologies: Opportunities and Uncertainties – Summary and Recommendations," The Royal Society, London, England, 2004, 4.
[4] The Royal Society, 5.
[5] Wolfgang Luther, ed., "Industrial Applications of Nanomaterials: Chances and Risks – Technological Analysis," Futures Technologies Division of VDI Technologiezentrum GmbH, Dusseldorf, Germany, 2004, 43.
[6] Luther, 43.
[7] Luther, 93.
[8] Hett, 43.
[9] Hett, 30.
[10] The Royal Society, 5.
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[12] Luther, 75.
[13] Luther, 75.
[14] Hett, 33.
[15] Hett, 34.
[16] The Royal Society, 9.
[17] Luther, 91.
[18] Luther, 78.
[19] Luther, 93.
[20] Hett, 36.
[21] Hett, 36.
[22] Hett, 37.
[23] The Royal Society, 6.
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[25] The Royal Society, 7.
[26] Luther, 94.
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[28] Hett, 47.
[29] Hett, 48.
[30] The Royal Society, 6.
[31] Luther, 91.
[32] Hett, 44.
[33] The Royal Society, 6.
[34] Luther, 94.
[35] European Commission, "Nanotechnologies: A Preliminary Risk Analysis," Health and Consumer Protection Directorate General of the European Commission, 2004, 22.