Abstract: Managing emerging risks, such as those posed by nanotechnology, is a challenge that requires carefully balancing largely unknown benefits and risks. Here we review current nanomaterial risk management frameworks and related documents, with a focus on identifying and assessing gaps in their coverage. We do so using a regulatory pyramid, with self-regulation at the pyramid base and prescriptive legislation at its apex. We find that appropriate regulatory tools, especially at the bottom of the regulatory pyramid, are largely lacking. In addition, we recommend that regulatory agencies employ an adaptive, tiered framework to manage nanotechnology risk. The framework should utilize multiple tools at different levels of the pyramid, with specific tools chosen on a case-by-case basis.

1. Background

Managing emerging risks poses a challenge to regulatory agencies because decisions must be made based on extremely limited information in the face of significant public scrutiny. Regulatory agencies worldwide have successfully implemented health and safety procedures to address environmental and occupational exposure concerns for traditional industrial materials. Newly emerging risks in the realm of nanomaterials may differ from past stressors, but they involve many similar issues, including public pressure, the necessity of making regulatory decisions, and a significant level of uncertainty regarding material properties and impacts throughout
product life cycles. For many emerging risks, regulatory agencies may need to modify their traditional risk management paradigm, explore innovative hazard identification and risk characterization methods and tools, communicate risks to the public, and integrate risk management with larger societal considerations during the decision-making process.

As with many new technologies, developing a framework for making risk management decisions with regard to nanotechnology is a challenge. Around the world, regulatory agencies, trade organizations, nonprofit organizations, academics, and members of industry are proposing nanomaterial risk management models and frameworks. This chapter reviews current risk management frameworks and related documents for nanotechnology. Many of the regulatory frameworks are designed to address a specific issue, industry, or single class of nanomaterials, and thus may not be directly relevant for every aspect of nanomaterial management. Even though the current knowledge base is limited, this review and evaluation allows identification of gaps in existing frameworks that may be important to managers and other stakeholders.

Thirteen frameworks and related documents were selected for in-depth review. Data were summarized according to criteria associated with each of our four categories, and narratives were developed that describe which documents pertain to which criteria. Preliminary identification of gaps—those criteria that are relatively unaddressed by the reviewed documents—and suggested approaches for formal gap prioritization are given after the review. Taken together, this information could provide the basis for selecting an instrument of choice for regulating nanomaterial risks.

2. Approach

We reviewed documents from a range of countries and purposes. We reviewed comprehensive state-of-the-science regulation framework documents, such as USEPA’s “Nanotechnology White Paper” [48], the Royal Society’s “Nanoscience and nanotechnologies” report [38], and the International Risk Governance Council’s “Nanotechnology Risk Governance” white paper [20]. We also reviewed documents for voluntary programs, such as the Environmental Defense-DuPont “Nano Risk Framework” report [15] and the Voluntary Reporting Scheme for nanomaterial information of the UK’s Department for Environment, Food and Rural Affairs [45]. J. Clarence Davies’s “Managing the Effects of Nanotechnology” [11] focuses on the regulation of nanomaterials, and the position statement “Ethics and Nanotechnology: A Basis for Action” from the Québec Commission de l’éthique de la science et de la technologie [35] gives an ethics-focused view of nanotechnology. A list of documents reviewed and the focus of each is provided below (Table 1).