While several US federal regulations are expected to apply to emerging nanomaterials, questions remain as to whether current regulatory frameworks are sufficient for managing risks that may emerge. This work investigates the federal health, safety, and environmental regulations that apply over the life cycle of a typical nanomaterial to determine whether novel properties and high uncertainty over risks significantly challenge the current regulatory system.

While existing regulations are widely considered to provide adequate authority to regulate nanomaterials, novel properties, low production volumes, sparse data, and a lack of standards and protocols severely challenge the applicability of regulations. Furthermore, a shortage of resources and inadequate authority to require testing or recalls severely limit regulators’ effectiveness in managing risk. Many nano-products as a result will go largely unregulated along their life cycle, while others may fall through gaps in regulation as they move from one stage of their life to the next. Overall, improvements in authority to require testing of a wider range of products, a systems approach to regulation that better engages stakeholders in risk management, and improvements in regulatory oversight at the ‘use’ stage are recommended.

Figure 1. Federal health, safety, and environmental regulations that apply along the life cycle of a typical nanomaterial. Dashed boxes denote the life cycle stages at which each regulation’s primary regulatory mechanisms are in effect.