International Symposium on Assessing the Economic Impact of Nanotechnology

Session Six: Exploring the Quantitative Dimension of the Economic Impact of Nanotechnology

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Economic Impact and Commercialization

- The economic impact of nanotechnology is directly relevant to the commercialization of nano-based products
- Why is this so? Pre-market approval is required of products under the jurisdiction of EPA (new industrial chemicals/agricultural chemicals/ antimicrobials) and FDA (direct/indirect food additives) and a "benefit" showing is essential

Toxic Substances Control Act (TSCA)

- TSCA regulates chemical substances, and new uses of existing chemicals, including new nanoscale chemical substances
- New chemicals, and new uses of existing chemicals, must be approved prior to commercialization

TSCA (cont'd)

- TSCA is a risk/benefit statute
  - This means EPA is authorized to approve a new chemical provided if the benefits are determined to outweigh potential risks
  - Unclear how EPA quantifies "benefits" for these purposes

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- FIFRA regulates chemical substances defined as pesticides, including antimicrobials
- FIFRA requires pre-market approval of new pesticides and new uses of existing pesticides
- FIFRA is also a cost benefit statute, which means EPA is authorized to approve a pesticide registration application if the benefits of the pesticide are determined to outweigh potential risks

FIFRA (cont'd)

- Unclear how EPA quantifies "benefits" for these purposes
- For example, EPA concludes that consumers purchasing textiles treated with nanosilver "may" receive more durable antimicrobial protection from nanosilver compared to alternatives even though there is less total silver in the nanosilver treated textile

Food Additives

- The Federal Food, Drug, and Cosmetic Act (FFDCA) provides FDA with significant pre-market control over food additives
  - Pre-market review of direct food additives
  - Pre-market approval of indirect food additives
- FFDCA prohibits introduction in commerce of adulterated food. Under the law, a food additive is deemed to be adulterated, and thus prohibited, unless FDA has acted affirmatively and determined that its intended use would be safe
- Unclear how FDA defines "safe" for these purposes, but certainly includes the concept of benefit

Conclusion

- Quantifying impacts is relevant to market approvals under TSCA, FIFRA, and FFDCA
- How regulators quantify impacts -- including benefits -- is crucially important
- Better tools are needed that are transparent, rational, and easy to apply
- Stakeholders must do a better job of developing and promoting these tools

Questions

- Identify and review current approaches to assessing economic impact of nanotechnology. What are their limitations? Are they broadly applicable? Are there sufficient data available?
- What is not currently being captured by metrics that should be?
- What is a reasonable objective to set for the economic assessment of the impact of nanotechnology in each sector in 3 or 5 years?

Thank You

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