International Harmonization of Nanotechnology Regulation

Gary Marchant, JD PhD
Center for Law, Science & Innovation
Sandra Day O’Connor
College of Law
Arizona State University
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Arguments for Harmonizing National Nano Regulations

- Uniform product standards facilitate international commerce/trade
- Multinational companies can apply consistent workplace, safety and environmental standards
- Potentially hazardous nanomaterials in environment may cross national boundaries
- Prevent trade barriers from inconsistent national regulations
- Prevent “race to the bottom” or “risk havens”
- Economies of scale for regulators
The GM Foods Lesson

- Disparate GM regulatory standards between US, EU, and other nations have caused enormous problems:
  - Restrictions in trade
  - Uncertainty and confusion
  - Recalls and embargoes
  - Liability and economic disruption
  - Shortages
  - Disincentives and skewed decision
  - WTO dispute
Disparate National Standards => Intractable Int’l Disputes

- “The transatlantic GMO dispute has brought into conflict two longtime allies, economically interdependent democracies with a long record of bilateral and multilateral cooperation in both economics and security. Yet the dispute has developed into one of the most bitter and intractable transatlantic and global conflicts, resisting efforts at resolution in bilateral networks and multilateral regimes alike, and resulting in a bitterly contested legal battle before the WTO.”
  - Pollack & Schaffer (2009)
National vs. Int’l Regulation: Which Comes First?

○ Francis Fukuyama:
  ● “[R]egulation cannot work in a globalized world unless it is global in scope. Nonetheless, national-level regulation must come first. Effective regulation almost never starts at an international level ....” *Foreign Policy*, Mar/Apr 2002.

○ But developing national regulations first may:
  ● unduly delay international regime
  ● be more difficult in the face of entrenched and inconsistent national regulations (e.g., GMOs)
Window of Opportunity? International Convergence

- Very few national nano specific regulations currently in effect
- Several countries have undertaken analyses to identify gaps in existing regulatory frameworks
- Some countries have launched voluntary reporting requirements (e.g., UK, Australia, Denmark, U.S)
  - generally poor response
- “New” vs. “existing” substances
- Rejection of labeling requirements
  - but recent EU actions on cosmetics, novel foods
- All nations emphasize importance of international coordination/harmonization
Traditional International Treaties and Agreements

- Treaties and other formal international agreements unlikely in near term for nanotechnology:
  - Negotiation of international treaty requires enormous commitment of resources, time and political capital
    - e.g., climate change/Copenhagen
  - Perceived as a future rather than current problem (no dead bodies)
  - Many other international priorities
“Transnational New Governance”

- Originates from soft law concept in international law
- Substantive obligations and requirements created by instruments that are not directly legally enforceable
- International scope/focus/participation
- Broadening oversight from top-down government requirements to include a much broader range of decision-makers
  - e.g., companies, NGOs, public-private partnerships, third parties
Advantages of Transnational New Governance

- Voluntary; cooperative
- Reflexive
- Can be adopted or revised relatively quickly
- Many different approaches can be tried simultaneously
- Can be gradually “hardened” into more formal regulatory oversight
Limitations of Transactional New Governance

- Norms/standards not directly enforceable
- Risk of “whitewashing” or “greenwashing”
- Participation limitations
- Not always as flexible and adaptable as hoped
- Potential for confusion/overlap
- Less legitimacy
Incremental, Cooperative, Reflexive Oversight

Initial Step: Transnational Dialogue

- OECD Working Groups
- Transatlantic Economic Council
- International Dialogue on Responsible Research and Development of Nanotechnology
- International Conference on Chemicals Management (ICCM)/Strategic Approach to International Chemicals Management (SAICM)
- International Conference on Harmonization
International Standards/Norms

- Standard-setting organizations (e.g., ISO)
- Dupont-EDF NanoRisk Framework
- Responsible NanoCode
- EU Code of Conduct for Responsible Nanotechnology Research
- CENARIOS® risk management certification
- Responsible Care program
- Other company/industry standards
International Scientific Assessment Body

- Create international expert body on scientific assessment of nanotechnology risk
- Model: Intergovernmental Panel on Climate Change (IPCC)
  - Question – lessons learned?
Future Step?
Framework Convention

- International agreement negotiated by States
- Establishes institutions, processes and procedures
- Minimal (if any) substantive content at first
- Encourage broad participation by as many states as possible
- Build trust
- Gradually add substance in the form of protocols
Framework Conventions: Benefits

- “In sum, the FC-protocol approach allows states to put in place activities and procedures designed to reduce scientific and technical uncertainty about a problem, and then to act incrementally to address that problem or particular aspects of it, as their knowledge and understanding grow. Politically, the substantive weakness of the original FC helps to attract the broadest possible participation, even if the commitment of some participants is weak or even insincere; as the process unfolds, the aim typically is to enmesh the participants in a process of social learning that will lead them to accept stronger commitments commensurate with the evolving understanding of the problem.”

Abbott et al., 2006
Challenges for Domestic “Hard Law” Nanotechnology Regulation

- Lack of enforceable definition
- Scientific uncertainty/data gaps
- Broad range of nanotechnology products and applications
- Rapidly evolving technology
- Obsolete statutory provisions
- Level playing field
Conclusion

- Soft law “new governance” approaches most feasible approach in short term at both national and international levels
- This convergence may open the door for more explicit focus/ emphasis on transnational mechanisms
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