

International Regulatory Initiatives Affecting Nanotechnology

Jeffrey H. Matsuura

March 1, 2007



**ALLIANCE
LAW GROUP_{LLC}**

www.AllianceLawGroup.com

Key Regulatory Approaches

- **Supportive regulations**
- **Integration of nanotech into existing regulations**
- **Consideration of new regulations**
- **Self-regulation**

Encouraging Nanotech

- **Some nations establish legal framework to support nanotech research and development**
- **Similar to U.S. National Nano Initiative**
- **Israel: National Nanotechnology Initiative (1999)**
- **Brazil: National Program for the Development of Nanoscience & Nanotechnology (2005)**
- **South Korea: National Nanotechnology Development Program (2003)**
- **Includes political support and funding for research**



**ALLIANCE
LAW GROUP_{LLC}**

www.AllianceLawGroup.com

Components of National Initiatives

- **National recognition of significance of nanotech research and applications**
- **Political statement of national will in support of nanotech work**
- **Funding for additional research**
- **Coordination of nanotech information**
- **Study of impact of nanoscience and nanotechnology (social, economic, etc.)**



**ALLIANCE
LAW GROUP_{LLC}**

www.AllianceLawGroup.com

Key Aspects of Regulatory Integration

- **Fundamental issue: Are existing regulations adequate?**
- **Efforts to assess the extent to which gaps exist in current regulatory framework**
- **Under what circumstances does nanotech require modifications to existing regulations?**
- **Application of current regulations until we know more about nanotech and its implications**



**ALLIANCE
LAW GROUP_{LLC}**

www.AllianceLawGroup.com

The Challenge of Uncertainty

- **Currently unable to assess the need for special nanotechnology regulations**
- **Inadequate data on impact available**
- **Premature to consider new rules for nanotechnology**
- **Effective assessment of special regulatory needs for nanotechnology requires more study and more data**



**ALLIANCE
LAW GROUP_{LLC}**

www.AllianceLawGroup.com

Self-Regulation

- **Conduct controls imposed by parties other than governments provide other options**
- **Industry organizations and other non-governmental groups can set conduct standards**
- **One example now in process, International Organization for Standardization (ISO)**
- **ISO Technical Committee 229 evaluating potential nanotechnology standards**
- **Development of industry standards can influence conduct without direct government action**



**ALLIANCE
LAW GROUP_{LLC}**

www.AllianceLawGroup.com

Government Guidance and Focused Incentives

- **Some governments attempt to influence nanotechnology work through informal means and development of incentives**
- **Facilitating information-sharing and coordinating commercialization efforts (e.g., Netherlands, China, Thailand, Taiwan, South Africa)**
- **Israel's Nanotechnology Trust: Fund to assist targeted research and commercialization in nano fields**
- **Government efforts to influence nanotech work without formal legal action**



**ALLIANCE
LAW GROUP^{LLC}**

www.AllianceLawGroup.com

The Future

- **Increasing number of countries likely to combine regulatory strategies for nanoscience & nanotech**
- **Must develop additional data on impact of nanotech use, current knowledge base inadequate for effective regulations**
- **Need to recognize that an expanding set of regulations will affect nanotechnology as applications diversify (e.g., technology export controls, trade rules)**



**ALLIANCE
LAW GROUP_{LLC}**

www.AllianceLawGroup.com

Regulatory Balance

- **Nanotech context illustrates an interesting apparent trend in technology regulation**
- **Regulation/legislation now commonly used by nations to promote research, consistent with national goals**
- **Regulation/legislation also controls/limits research and application of research, at times**
- **Nations struggling to balance these competing policy interests**
- **Regulatory balance a challenge for many emerging technologies**