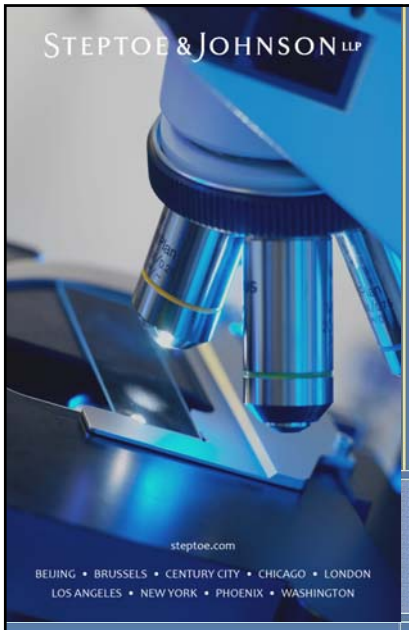


Liability Insurance: Diverse and Complex Issues, Complex and Diverse Solutions

Nanotechnology Overview

Dr. Anna Gergely, Director EHS Regulatory
agergely@steptoe.com

12th-14th September 2011 Cambridge

STEPTOE & JOHNSON LLP

CONTENT

1. Why is "nano" a challenge
2. Regulatory developments for the governance of nanotechnologies
   - The Risk Assessment Paradigm
   - Risk Management Options
3. Industry's due diligence – how to mitigate risk
4. Is "nano" insurable?
5. Conclusions

WHAT IS AT STAKE?

- There is no agreed definition yet, but in principle nanotechnologies involve the ability to manufacture, process, and apply materials that have **one or more dimensions** of the order of **100 nanometers (nm) or less**

1 nm = 1 billionth of a meter

- 1/5,000,000 the size of an ant
- 1/80,000 of the diameter of a human hair
- 1/90 the size of HIV virus

→

- Physical and chemical rules may change at nano-scale
- Materials may behave differently than bulk analogue

↓

- **Novel materials, applications and consumer/ industrial products**

THE NEXT INDUSTRIAL REVOLUTION

- **Unlimited potential**→Fundamentally new scope for products and their manufacturing
- ***"Increasing economic value*** *of nanotechnologies in different market sectors, proliferation of* ***innovation****, as reflected in* ***patent filings****, and expanding* ***investment*** *in research by both private companies and national governments all suggest that nanotechnology is to assume an ever-expanding investment in industrial society."*

  [LSE project funded by the European Commission on transatlantic regulatory co-operation in the field of nanotechnology, September 2009]
- Market impact likely to exceed 1 trillion US$ by 2015

Selected Examples: Nanotechnologies Across the Product Markets…

❖ Energy and Climate Protection

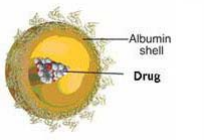
Examples

- **Bayer AG**: Rotor blades containing Baytubes® carbon nanotubes for increased power yields and ability to withstand hurricane-strength wind speeds – basis of the wind power systems Hybtonite® manufactured by Eagle Wind Power, Finland.
- **US Department of Energy**'s Hydrogen Program (in partnership with industry, academia, national laboratories, federal and int'l agencies): R&D in hydrogen production, delivery, storage, and fuel cells.

Selected Examples: Nanotechnologies Across the Product Markets…

❖ Pharmaceuticals and Medical Devices

Examples



- **Abraxis** *nab*™ Technology: protein nanoparticles suitable for in vivo delivery of potentially broad range of drugs (improved delivery)
- A new approach to detect rare cancer cells using magnetic nanoparticles and gold-plated carbon nanotubes
- Initial tests on early and reliable field detection of viruses, E. coli, DNA, proteins, antibodies etc. through carbon nanotubes-based sensors or fluorescent nanoparticles and core-shell particles

Selected Examples: Nanotechnologies Across the Product Markets…

❖ Electronics

Examples

- **HP**'s nanoimprint lithography – printing method that allows an entire wafer of circuits to be stamped out quickly and inexpensively from a master template

❖ Automotive and Construction

Examples

- **Pilkington**: Pilkington Activ™ Self Cleaning Glass with a nano layer that breaks down dirt
- **Bayer AG**: Baytubes® carbon nanotubes are used for automotive industry, e.g. PA fuel line, PPO/PA car body panel
- **DaimlerChrysler**®: Paint finish with improved scratch resistance

Selected Examples: Nanotechnologies Across the Product Markets…

❖ Consumer Products

Examples

- **BASF**: Mincor® TX TT – textiles such as awnings, sunshades, sails and tents with a self-cleaning effect
- **Ecology Coatings, Inc.** (in collaboration with a major tobacco company): Fire-safe cigarettes
- **Wilson Sporting Goods**: Tennis ball Double Core™ - to prevent air escaping from the core of the ball
- **L'Oreal**: Anti-wrinkle cream RevitaLift® Double Lifting containing nanoparticles of Pro-Retinol A

Selected Examples: Nanotechnologies Across the Product Markets…

❖ Food, Beverages and Packaging

Examples

- **Melitta**: Toppits Back ® - aluminum foil with a nanotechnology-enabled coating which reaches higher surface temperatures when cooking, food is prepared quicker (up to 30% of the normal cooking time)
- **Miller Brewing**: Plastic beer bottle made using clay nanoparticles as a gas barrier to improve shelf-life
- **RBC Life Sciences®, Inc**.: Slimming chocolate shake that uses nanoclusters of cocoa to enhance the flavour while reducing the sugar content

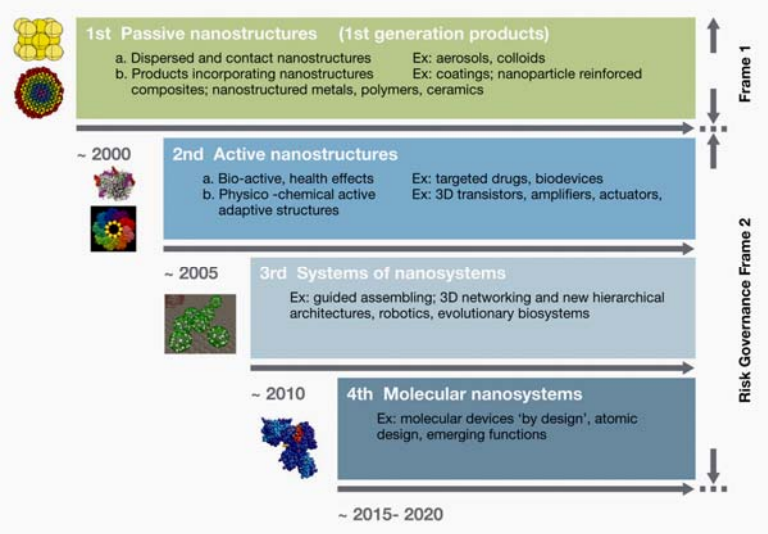
DISTRIBUTION OF APPLICATIONS

- Cosmetics and personal care products ~60%
- Paints & coatings ~10%
- Catalysts & lubricants
- Security printing
- Textiles & sports
- Medical & healthcare
- Food and nutritional supplements ~10%
- Food packaging
- Agrochemicals
- Veterinary medicines
- Water decontamination
- Construction materials
- Electrical & electronics ~10%
- Fuel cells & batteries
- Paper manufacturing
- Weapons & explosives

*Source: www.nanotechproject.org/inventories/consumer/

FOUR GENERATIONS OF NANOTECHNOLOGY

(Courtesy: International Risk Governance Council, 2009)



NANO: BENEFITS

- Promise of advanced new materials and new applications in key areas such as electronics, pharmaceuticals, chemicals, engineering, aerospace, defence
- Promise of improved human health, extended lifespan, enhanced physical capabilities
- Promise of sustainability by cleaner energy, environmental remediation, water purification, improved food production
- Promise of economic growth and job creation

- **Global opportunities require coordinated approach**

NANO: RISKS

- Human health (workers' and consumers' safety)
- Environment (potential immediate and long term effects)
- Disruptive nature of the technology (potential new industries; new economical powers; changes in labour markets)
- Responsibilities and Liabilities (regulatory oversight; accountability)
- Civil Liberties (privacy issues; right for individual choice)
- **Challenges also need to be addressed globally**

"NANO" CHALLENGES

- Is "nano" a class of its own? Are there any "nano-specific" risks - liabilities?
- Broad in scope - knowledge is fast evolving
- No consensus on definition, nanomaterial characterization, surface treatment etc.
- Lack of harmonized EU regulation - potential proliferation of national legislation
- Lack of trust between stakeholders – need for communication

RISK ASSESSMENT PARADIGM

Intrinsic properties: interaction health and environment

HAZARD

X

Widespread applications and increased potential for

EXPOSURE

Pressure for regulatory oversight:

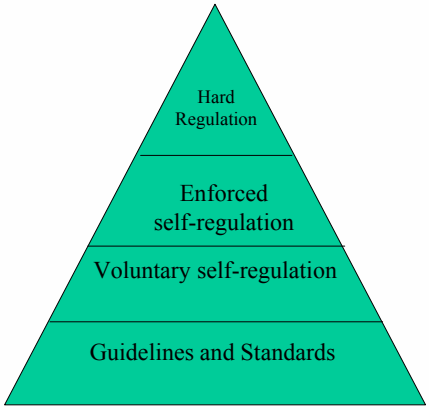
- Total moratorium until the technology is proven safe?
- Existing regulatory framework is sufficient to control use while it is industry's ultimate responsibility to only place safe products on the market?

► **Global regulatory oversight is needed**

THE REGULATORY PYRAMID

- Observatory Nano Project:

http://www.observatorynano.eu/project/filesystem/files/DevelopmentsInNanotechnologiesRegulationandStandards_2011.pdf:



THE REGULATORY PYRAMID (cont.)

- On top: hard regulation, enforced by regulatory authorities
- Under it: enforced self-regulation (such as mandatory reporting schemes, data call-ins)
- Below: voluntary self-regulation (codes of conduct, industry risk management systems, reporting schemes
- Base level: guidelines and standards (ISO, OECD, government authorities)

"HARD" REGULATION

- **Horizontal Legislation:** (applicable, but pre-nano)
  - ✓ General Product Safety and Product Liability Legislation
  - ✓ Workers' Protection Legislation
  - ✓ Environmental Legislation
  - ✓ Chemicals Legislation (REACH and CLP)
- **Vertical (Application Specific) Legislation:** (nano-specific)
  - ✓ Food / Novel Food / Food-contact
  - ✓ Cosmetics
  - ✓ Biocides
  - ✓ RoHS
  - ✓ Medical Devices etc.

HARD REGULATION: EXISTING LEGAL FRAMEWORK

- **Horizontal Legislation: PRODUCT LIABILITY DIRECTIVE (85/374/EEC)**
  - ✓ (Article 1) *The producer shall be liable for damage caused by a defect in his product*
  - ✓ (Article 4) *The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage*
  - ✓ (Article 6) *A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:*
    - *(a) the presentation of the product;*
    - *(b) the use to which it could reasonably be expected that the product would be put;*
    - *(c) the time when the product was put into circulation.*
  - ✓ (Article 7) *The producer shall **not be liable** as a result of this Directive if he proves:*
    - *(e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered;*

HARD REGULATION: EXISTING LEGAL FRAMEWORK

- **Horizontal Legislation: REACH REGULATION (1907/2006)**
  - ✓ Covers all substances; also in nano form
    - *Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process* [..] Article 3(1)
  - ✓ Provides options for further data requirements and even for authorization or restriction
  - ✓ No registration requirement if < 1MT/year (together with bulk equivalent)
  - ✓ Nanoforms of existing bulk equivalents were not "new" substances; hence no registration requirements until relevant phase-in deadlines (June 2018, the latest)

REACH (cont.)

- Extensive implementation projects (RIP-oN) to cover
  - Substance identification
  - Information requirements
  - Chemical Safety Assessment
- ✓RIP-oN1 to define nanomaterials based on relevant case studies (CNT; nAg; nTiO2; nCaCO3); to provide information on the relevant parameters for nanomaterial identification
- ✓RIP-oN2 and 3; draft guidance documents
- ✓Need for agreed definition to determine scope

EXISTING LEGAL FRAMEWORK - FOOD

- **Vertical Legislation: FOOD REGULATION (178/2002):**
- General principle of food law: 'Food shall not be placed on the market if it is unsafe' (Article 14(1))
- Regulation of products or processes that incorporate nano, not nanotechnology itself
- Existing 'precautionary approach' prior approval food legislation (process/product specific)

EXISTING LEGAL FRAMEWORK - ADDITIVES

- **Food Additives Regulation 1333/2008:**
  - In conjunction with Regulations on food enzymes (No. 1334/2008) and on food flavourings (No. 1334/2008), a common authorization system is introduced and a common basis of control is established
  - Food additives produced through nanotechnology require separate new entry in positive list from non-nano version already on list (Article 12)
  - Producers or users of a food additive are obliged to inform the Commission of any new scientific or technical information that may affect the safety-assessment of the food additive (Article 26)

EXISTING LEGAL FRAMEWORK - FOOD CONTACT

- **Regulation 1935/2004 (Framework Regulation):** specific provisions on safety – also applies for nanomaterials
  - ✓ Further, the Framework Regulation also provides, that: *...the applicant or any business operator using the authorized substance shall immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorized substance in relation to human health.*
- **Regulation 10/2011 (Plastics Regulation – ex PMI):**
  - ✓ *Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I*
  - ✓ *Substances in nanoform are treated as potential CMRs*
  - ✓ the positive listing of a substance may not be claimed to also cover its nano-form

EXISTING LEGAL FRAMEWORK - COSMETICS

- **Cosmetics Regulation (EC) No 1223/2009**
  - ✓ Amended to specifically address nano materials (applies from 11 January 2013)
  - ✓ Intention to place a product containing nanomaterials on the market must be notified to the Commission 6 months in advance (no obligatory assessment by the SCCS)
  - ✓ "Moving" definition for nanomaterials: "*insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure on the scale of 1 to 100 nm*" – to be adapted if international agreement
  - ✓ Catalogue of all nanomaterials in cosmetic products by 11 January 2014
  - ✓ Labelling of all nano ingredients (name followed by "nano" in brackets)
  - ✓ Substances listed in Annexes do not cover nanomaterials, unless specifically mentioned (REACH consistent?)
  - ✓ "Precautionary principle" in absence of relevant scientific evidence

"SOFT" REGULATION: CODE OF CONDUCT

- *The protection of human life and the environment is a fundamental principle for our company.*
- *We identify sources of risk for our employees and eliminate these using the appropriate measures and take immediate action. In parallel with technological progress we work continuously to identify potential environmental and health risks.*
- *We are actively involved in the ongoing development of a scientifically based database for the assessment of potential risks as well as in improving and refining product-based testing and assessment methods.*
- *We contribute constructively to drawing up legislation. Our goal is to establish risk-appropriate, solid standards and to support relevant legislation.*
- *In our Values and Principles, we have committed ourselves to pursuing a dialogue with society based on openness and trust. We regard it as our duty to provide information about both the opportunities and the potential risks of nanotechnology.*

[Extracts from BASF]

"SOFT" REGULATION: NANO RISK FRAMEWORK

- DuPont in partnership with Environmental Defence (Environmental NGO)
- A comprehensive tool:
  - ✓to organize, document and communicate what the user knows about the material;
  - ✓to acknowledge where the information is incomplete;
  - ✓to explain how information gaps were addressed; and
  - ✓to show the rationale behind the risk management decisions and actions.

REGULATORY DEVELOPMENTS - DEFINITIONS

- Definition is a prerequisite of regulation – but there is no agreed definition yet
- Definitions are already adopted in EU law (Cosmetics, failed draft Novel Food -now draft Food Information Regulation, Food Contact, draft Biocides, etc.)
- International developments (ISO, OECD Working Party on Manufactured Nanomaterials (WPMN)
- National level (EU Member States, US, Australia, Canada etc.)
- However, existing or proposed definitions are **not** based on the same elements or even a similar approach
  - ✓ strict definition OR flexible trigger points?
  - ✓ focus on novel functionality, not size range?
  - ✓ list of properties that are characteristic of the nanoscale?
  - ✓ distinguish between "naturally occurring" and engineered nanoparticles?
- Creates regulatory uncertainty

EU REGULATORY DEVELOPMENTS - DEFINITIONS

- **European Commission Draft Recommendation** (was open for public consultation until 19 November 2010 but still not concluded):
  - Consists of particles, with one or more external dimensions in the size range 1nm – 100nm for more than 1% of their number size distribution
  - Has internal or surface structures in one or more dimensions in the size range 1nm-100nm
  - Has a specific surface area by volume greater than $60m^2/cm^3$, excluding materials consisting of particles with a size lower than 1nm
    - Particle: means a minute piece of matter with defined physical boundaries (ISO 146446:2007)
- In its present form this draft definition would cover the majority of products around us!

DEFINITIONS (cont.)

- **Industry position** (ICCA and CEFIC)
  - ✓Particulates
  - ✓Intentionally manufactured (engineered) at the nano-scale (1-100 nm), as per ISO standard
  - ✓Covers aggregates and agglomerates
  - ✓Cut-off limit either:
    - 10 w% or more nano-objects (as per ISO) OR
    - 50 w% or more of aggregates/agglomerates of nano-objects

EU REPORTING / INVENTORIES

- Belgian Presidency (2010) proposes to establish nanomaterials register under REACH
  - ✓ mandatory to label nanomaterials in consumer products
- 2009 Milieu Report commissioned by Commission proposes Commission mandatory nanomaterials register
  - ✓ information from producers/importers required to understand what is on market and assess exposure
- Some Member States (lead by BE, IT and FR) work towards "harmonized national databases" for nanomaterials on the market

POSITION OF THE EUROPEAN PARLIAMENT

- April 2009 Resolution on regulatory aspects of nanomaterials; among others:
  - ✓ Call on Commission to review all relevant legislation within 2 years (2011)
  - ✓ Introduce comprehensive definition of nanomaterials into relevant Community legislation
  - ✓ Commission to compile before June 2011 publicly available inventory (respecting CBI) of different types/uses of nanomaterials in EU
  - ✓ Labelling of nano ingredients
  - ✓ Urgent development of adequate testing protocols to assess hazards of and exposure to nanomaterials
  - ✓ Duty of care on manufacturers placing nanomaterials on the market

NANOTECHNOLOGIES GOVERNANCE OPTIONS

- Proper governance should include all viable regulatory options; voluntary measures and mandatory requirements; and should be based on an international consensus. Isolated efforts may result in trade disputes
- Early, non-mature mandatory rules may be counter-productive, resulting in regulatory discrepancies
- As the interest of responsible industry to place safe products on the market drives towards minimized risk; governance should integrate voluntary industry standards
- The common industry interest in effective and knowledge-based regulatory oversight should drive cooperation to produce and share reliable data with authorities ensuring "good" regulation and consumer trust

Nano*futures*

- "Nano-Hub": Industry-driven initiative for the sustainable development of nanotechnologies via cooperation for addressing horizontal issues (safety, regulation communication, etc.)
- Multi-sectoral, cross-ETP integrating platform
- Objective: Co-ordinate research efforts, address all horizontal issues, ensure societal acceptance
- Openness: open to EU industry, SMEs, NGOs, financial institutions, research institutions, universities, civil society
- Close co-ordination with European Commission (DG Research)

Further information at http://www.minamwebportal.eu/index.php?m1=Public-Area

INDUSTRY'S DUE DILIGENCE

- Risk assessment is left to the business operator
- Safety could be demonstrated on a case-by-case basis:
  - ✓sufficient hazard information
  - ✓ lack of exposure
- Requires proper product stewardship through the entire life-cycle of the product
- More and more individual authorization of the nano-form is required by the relevant Authority

IS NANO INSURABLE?

- Areas of concern:
  - ✓Occupational
  - ✓Environmental
  - ✓Product related
- Scope of potential liability coverage:
  - ✓General liability (all inclusive)
  - ✓Product liability
  - ✓Pollution liability
  - ✓Product recall liability

  [Example: Lexington Insurance Company]

NANOTECHNOLOGY INSURANCE CHALLANGES

- Knowledge gap (novelty and complexity may create uncertainty)
- Lack of experience (no known past scenarios)
- Difficulty to anticipate and recognize risk with a long-tail event
- Moving target, with "state of the art" knowledge evolving fast
- Perception - may elevate risk potential

NANO INSURABILITY

- Information is a prerequisite:
  - ✓Risk selection
  - ✓Risk rating
  - ✓Risk premium
- These elements are normally based on previous experience
- Example: Asbestos

THE ASBESTOS STORY

- 1900 First evidence: risk became apparent; first reported deaths cases
- 1900 – 1930 Scientific publications
- 1931 First regulation; UK
- 1950-60 Asbestosis is recognized as occupational disease; first lawsuits filed for compensation
- 1975 First asbestos ban; Sweden
- 1985-2005 Stop using asbestos; rising litigation (estimated total cost of mass tort $ 200-260bn)

NANO IS INSURABLE

- Recommended steps to <u>demonstrate insurability</u>:
  - ✓ Compliance with all regulatory requirements
  - ✓ Reliable data on hazard and exposure
  - ✓ Information on workers protection; PPEs. Documented monitoring and control of workplaces
  - ✓ Procedure to monitor and manage changes
  - ✓ Product life cycle monitoring
  - ✓ Demonstrate traceability/record keeping
  - ✓ Strategy for handling adverse events
- Issues with:
  - ✓ Case-by-case risk assessment
  - ✓ State-of-the-art knowledge

STATE OF THE ART KNOWLEDGE DEFENCE

- One of the most controversial points in the asbestos lawsuits relates to the defendant (typically the industry)'s knowledge of the potential for hazards associated with asbestos exposure (see Product Liability Directive; *infra*)
- The defendant's liability is therefore linked to the state-of-the art knowledge of the risk at the time of the exposure to asbestos

RISK ASSESSMENT

- February 2009 EFSA opinion on the Potential Risk Arising from nanoscience and nanotechnologies on Food and Feed Safety:
  - ✓ The risk assessment of ENMs must be performed on a case-by-case basis
  - ✓ The available data on oral exposure to specific ENMs and any consequent toxicity are extremely limited
  - ✓ Under these circumstances, any individual risk assessment is likely to be subject to a high degree of uncertainty. This situation will remain so until more data or and experience with testing of ENMs becomes available

RISK ASSESSMENT

- New data may be needed to cover:
  - ✓ nano-specific characteristics of nano materials; such as particle size, form, flexibility, surface treatment, charge etc.
  - ✓ possible interaction with the environment
  - ✓ storage conditions prior use and waste cycle effecting these characteristics
  - ✓ concentration (mass, number and surface area related) of nanoparticles in the final product and their form (free or bound; surface or bulk etc.)
  - ✓ potential new endpoints
  - ✓ potential new target organs
  - ✓ potential new mechanisms

RISK ASSESSMENT - EFSA GUIDELINES

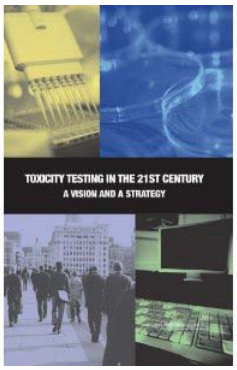
- Scientific Opinion published on 9 May 2011 (after public consultation)
- Covers: food additives, enzymes, flavourings, food contact materials, novel foods, feed additives and pesticides
- Risk assessment paradigm (Risk = Hazard x Exposure) is considered applicable
- Characterization of ENMs in five stages: (i) pristine state (as manufactured); (ii) as delivered to be used in food/feed; (iii) as present in food/feed matrix; (iv) as present in biological matrices; (v) as tested in tox testing;
- Risk determined by: chemical composition, phys-chem. properties; interaction with tissues and potential exposure (which contributes to the extent of hazard characterization)

EFSA GUIDELINES (cont.)

- Six approaches to tox. testing:
  - ✓ ENM is not present in food/feed due to (a) degradation; (b) no migration: No additional testing
  - ✓ ENM is transformed before ingestion: testing for non-nano form
  - ✓ ENM transformed in the gastro-intestinal tract: same as above
  - ✓ ENM persists, but there is info on the non-nano form: compare info for both (ADME)
  - ✓ ENM persists and no info on non-nano form: full testing
- *In vitro* and *in vivo* studies; some need modification – follow EFSA Guidance
- (new) "Uncertainty analysis" (characteristics; hazard; exposure)

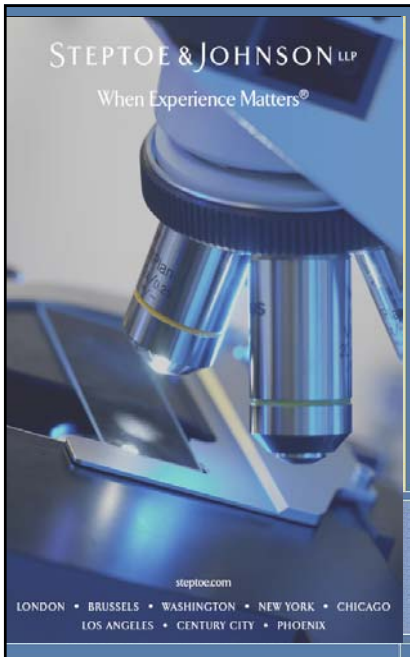
TOXICITY TESTING IN THE 21ST CENTURY: A VISION AND A STRATEGY

- 2007 National Research Council report outlines EPA vision for the future of tiered toxicity testing – moving from a top-down to a bottom-up system that relies preliminarily on *in silico* and *in vitro* screening, followed by targeted animal testing and population-level "surveillance" (such as biomonitoring and epidemiology)
- High-throughput robotic screening system stationed at NIH Chemical Genomics Center will rapidly screen thousands of chemicals (including nanomaterials)
- Tox21 Collaborative: NCGC, EPA, FDA and National Toxicology Program



CONCLUSIONS

- Lot is at stake: Nanotechnologies offer huge opportunities – exclusion is not a viable, long-term option
- Regulatory framework and appropriate liability coverage need to balance the economic potential with both ensuring safety and gaining public trust (avoid GMO backlash)
- EU legislative framework clearly covers nanotechnologies – must comply. But there are other factors to monitor
- The devil is in the details; for nano-specific risk assessment:
  - ✓ Identify precisely the nanotechnology being applied (per existing definition)
  - ✓ Develop appropriate risk assessment tools
  - ✓ Follow technical developments
- Ensure proper communication with all stakeholders, including the insurance industry



THANK YOU

http://www.steptoe.com/nanoresourcecenter

Dr. Anna Gergely, Director EHS Regulatory
agergely@steptoe.com

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