



KATHOLIEKE UNIVERSITEIT  
**LEUVEN**

# *NANOMARE* OR MAN'S ULTIMATE DREAM FOR CENTURIES ?

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# Overview of Presentation

- **Why should we care about the law**
- **What the law looks like**
- **What the law could /might /should look like**
- **Conclusion**



## Why should we care about the law

- *Business leaders are concerned about future liability issues emerging from three key sources: advances in technology, environmental damage and corporate governance. (...) Of greatest concern overall are the risks associated with technology - such as data and system security and nanotechnology- where the understanding of risks may not keep pace with the speed of innovation.*

Source: Lloyd's of London /EIU, *Directors in the dock: Is business facing a liability crisis?*, May 2008

- *Das eigentliche Risiko (liegt) in der Beherrschbarkeit der nanotechnologie*

Source : Nanotechnologie – Was kommt auf uns zu?, Munich Re, 2002



## Why should we care about the law ctd

- *whereas presentations about the potential benefits of nanotechnologies predict an almost infinite diversity of future applications of nanomaterials; however, the same diversity shrinks to near zero when it comes to a regulatory discussion about nanomaterials*
- *'Whereas nanomaterials are likely to be the next "big thing", especially given that manipulating all matter has been man's ultimate /dream for centuries*

Source : European Parliament draft report on regulatory aspects of nanomaterials, January 2009 ; confirmed by eventual resolution



## Why should we care about the law ctd

- Altruistically : environment, human health
- Selfishly: need for stable research and investment environment
- *Cf.* biotech/GMOs



## Why should we care about the law ctd

- Alert over the march of the 'grey goo' in nanotechnology Frankenfoods : Daily Mail , January 2008
- The beauty creams with nanoparticles that could poison your body : Daily Mail , November 2008
- “Carbon nanotubes as bad as asbestos, says study”  
Indo-Asian News Service, May 21, 2008
- “Carbon nanotubes may be as hazardous to health as asbestos”  
Guardian Unlimited, May 20, 2008
- Nanotech could cause mesothelioma”  
ABC Premium News, May 21, 2008

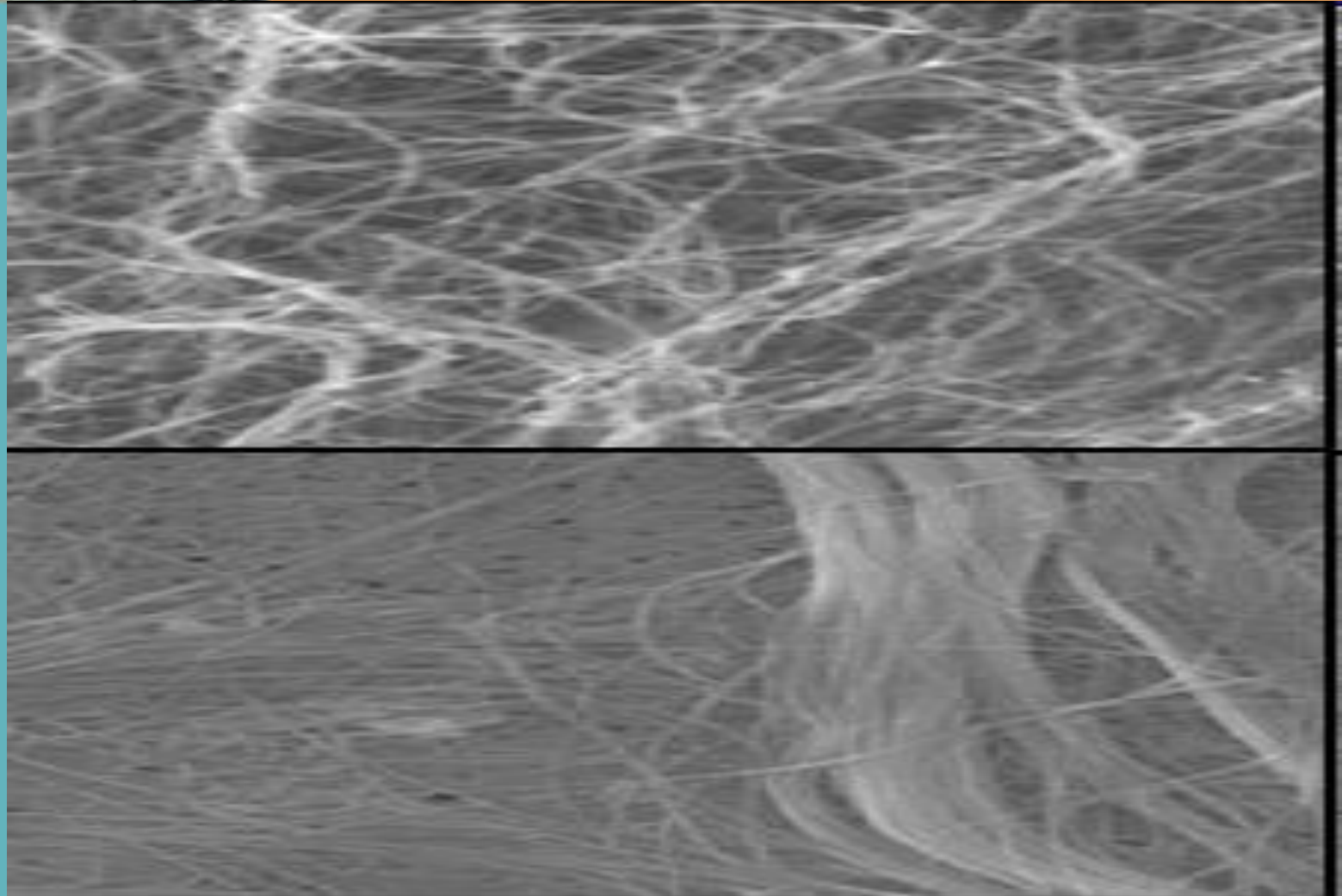


## What the law looks like

- No specific, tailor made law
- $\neq$  *no* law applies
- At the very least: product liability law, and ‘duty of care’, using the benchmark of the ‘*bonus pater familias*’ ; also various sectoral legislation which at least in theory covers any ‘nano risk’ : eg medical applications , pharmaceuticals , cosmetics (although notoriously underregulated) , foods...



## What the law looks like ctd





## What the law looks like ctd

- Carbon nanotubes showing similarities with asbestos fibres : *For a fibre to be harmful, it has to be thin, long and insoluble in the lung* : Ken Donaldson , University of Edinburgh [BBC News 20 May 2008, viz 'Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study', Craig A. Poland, Rodger Duffin, Ian Kinloch, Andrew Maynard, William A. H. Wallace, Anthony Seaton, Vicki Stone, Simon Brown, William MacNee & Ken Donaldson, Nature Nanotechnology 3, 423 - 428 (2008)



## What the law looks like ctd

- Until recently : no specific nano pointers in any legislation , worldwide. Some local initiatives (eg famously Berkeley : notification duty) on HS grounds mostly.
- Recent exception : REACH Regulation : removal of exception for all carbon as it occurred 'naturally'
- Recent exceptions : European Parliament calls for specific risk assessment for NT processes used in novel foods , as well as labelling for all nanoMTs ingredients ; and in the same week , similar proviso for use of Nano MTs in cosmetics , and a world's first (more or less) definition of Nano MTs :
- *"nanomaterial" means an insoluble or bioresistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm".*
- Note : no pre-market registration for cosmetics (cf. REACH)



## What the law can /may look like in the future

- ‘Modern’ environmental law and the impact of the precautionary principle
- famously : Late lessons from early warnings: the precautionary principle 1896-2000, European Environment Agency : ia DES , Halocarbons , MTBE , TBT , asbestos
- Legal status
- Reversal of burden of proof?



## What the law can /may look like in the future ctd

- Participation principles, ia of the 'Aarhus process'
- Environmental 'governance' generally: ia avoiding knowledge apartheid
- Ethics and the regulatory spectrum : the European Code of Conduct : C(2008) 424



## What the law can /may look like in the future ctd

- Regulatory co-operation?
- ‘Positive’ v ‘negative’ harmonisation: creation of a level playing field
- In the nano field, not just a free trade driver, but also necessary given the military dimensions of some of the technology
- Early signs of (transatlantic) regulatory co-operation evaporating ; background issues : different view of risk analysis stages (EU : risk management = political stage) ; conversely : more preparedness for litigation and judicial review in EU : see eg trade unions v EPA and TSCA



## What the law can /may look like in the future ctd

- Room for regulatory innovation?
- Ie move away from ‘command and control’
- Front-runner legislation?
- Who is ‘the’ industry: see eg classic issue of big industry v SMEs



## Conclusion

- **[Back to basics]** There is an urgent need to ensure the proper interpretation of scientific studies by those with regulatory responsibilities. As the overall amount of studies into toxicity etc increases, so too will there be an increased potential for scaremongering. Sound science is the starting-point for any regulation, and it is paramount for one to have a properly informed view as to where Safety, Health and Environmental risks of nanotechnologies really lie;
- **[Integrated approach]:** While immediate concerns with most commentators lies with (occupational and public) health and safety, the impact of nanotechnologies on the environment is equally poorly understood. Authorities have quite a bit up catching up to do in order properly to map the environmental issues



## Conclusion ctd

- **[Within the integrated approach: focus]** The European Parliament has already managed to galvanise industry into realising that a more focused risk assessment for nanotechnologies is of absolute essence. In chemicals, the application of the ‘no data, no market’ rule, results in and indeed is in part designed to lead to substances being withdrawn from the market. Both industry and regulators ought to focus on area where science does indicate potential hazard and risk. Insoluble nanoparticles would seem a good primary focus.
- **[Re-engage in regulatory convergence, and in coalition-building]** Both convergence between the various national regulatory regimes for nanotechnologies, and engagement between industry and stakeholders, featured highly in the initial debate on nanotechnology regulation. Both are now on a much lower burner and ought to be rekindled.



## Conclusion ctd





## Conclusion ctd





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