

http://www.reedsmith.com/files/Event/b1dd92dc-335a-4f27-a799-578bc0e871c4/Presentation/EventAttachment/2642f943-c397-435f-8b79-6803b8bcc95d/Nanotech_Teleseminar_PPT_transcript.pdf

Reed Smith's Nanotechnology Teleseminar:

New Environmental, Health and Safety Developments – The Silver Nanoparticles Case Study

Reed Smith's Nanotechnology Teleseminar Transcription

January 16, 2007

Jennifer (Operator): Hello and welcome to Reed Smith's Nanotechnology Teleseminar. All participants will be in listen-only mode. There will be an opportunity for you to ask questions at the end of today's presentation. If you should need assistance during the conference, please signal an operator by pressing star and zero on your touch tone phone. For your information, this conference is being recorded.

...**Paul Llewellyn:** Thank you, Tony. If you look at my first slide, you will see that the subject is nanotechnology and the EU. Because of the scientific and legal uncertainties and the limited time available, I am not going to deal with the substantive law. **I will look at the economic and regulatory context in which nanotechnology is developing in the EU. The EU is regarded by many US manufacturers and their lawyers as a rapidly expanding collective organization of disparate states whose language, culture, institutions, and economic performance vary enormously. As of January 2007 there are now 27 member states of the EU. There is also a widespread different view of the EU, a perception that it is overregulated, and is becoming more so.** The REACH regulation, the registration, evaluation, and authorization of chemicals will take effect in July 2007, although the transitional arrangements will take many years to complete. It is thought to be the apotheosis on nadir, depending on your viewpoint, of a regulatory impulse that is vigorous or out of control, again depending on your viewpoint. The regulation runs 846 pages. It has been hailed or condemned, according to preference, as the largest and most complex legislation to be introduced in Europe.

Another _____ of those who see the EU regulatory regime as overblown, and antithetical to business is the precautionary principle, the principle that determines when regulatory action is instituted by the EU, or by member states. **A Washington legal foundation report of November 2006, by Lawrence Kogan of the Institute for Trade Standards and Sustainable Developments, was entitled Exporting Precaution: How Europe's Risk Free Regulatory Agenda Threatens American Free Enterprise. The report describes how, and I quote**

“international bureaucrats and influential activist groups used the precautionary principle as a vehicle to diminish America’s competitive position in the global economy, and advance special interest agendas hostile to free enterprise and technology.” It all looks rather grim for nanomaterials in the EU, you might think in the circumstances.

(pp. 15-16)

...Does the precautionary principle threaten the implementation of the EE policy? This is on the next slide. The precautionary principle has three essential strands. First, any assessment of the risk to environmental and human safety should be based on scientific and technical data. Secondly, recourse to the principle requires identification of the potentially negative effects of any technology, and a scientific evaluation of the risk which, because of the insufficiency of the data, it’s inconclusive or imprecise nature makes it impossible to determine with sufficient certainty the true nature and extent of the risk. Thirdly, and finally, in determining whether to invoke one of the wide range of actions available under the precautionary principle, decision makers must act proportionally and consistently after examining the benefits of action or inaction. It is easy to cite instances of the questionable application of the precautionary principle, but the principle itself is unexceptional. It represents a balanced approach, and in rapidly developing technological world, with a myriad of risks, it is entirely appropriate. **The diagnosis of Lawrence Kogan, that the precautionary principle is a threat to American free enterprise seems in the context risible, and hyperbolic.** My view is, is that the precautionary principle, particularly as it has evolved in an EU, ever conscious of the need to maintain competitiveness in a global market will not in practice be an inappropriate or hindering criterion for the assessment of nano sciences and nanotechnology.