IOM's National Cancer Policy Forum
Policy Issues in Nanotechnology and Oncology,
July 12-13, 2010, Washington DC

Crossroad of Nanomedicine: Nanosafety and Policy

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The organizer's design of this session

- **Speakers are asked to address the following questions:**

— What lessons can US regulators learn from regulation of NT in other countries?

— What policies support cooperative research internationally?

— What policies support product development and regulation internationally?

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Outline of the Talk

1. Nanomedicine: multi-challenges

2. Nanosafety and Policy:
   The Roadmap and the solutions

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12 Big Challenges in Cancer Nanotechnology

Challenge 1. To make nanoparticle carriers easily get to a right place of the body (like tumor site), and to control a right release of nanoparticles

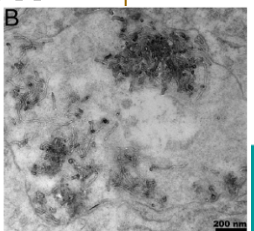
Challenge 2. To utilize nanoparticles directly as cancer medicine (simpler system, more efficient, easier control, lower toxic, smaller size, ……)

Challenge 3. To use nanoparticles enhancing performance of clinic medicines

Challenge 4. To develop multifunctional therapeutics

Challenge 5. To track and quantify nanoparticles in a specific organ of the body

Challenge 6. To prevent from nonspecific protein adsorption of nanoparticle, and then aggregation in vivo



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12 Big Challenges in Cancer Nanotechnology (Cont.)

Challenge 7. To escape from nanoparticle uptake and retention by RES (reticuloendothelial system like liver and spleen)

Challenge 8. To understand explicitly how nanoparticle works in vivo, and identify metabolism products of NPs

Challenge 9. To develop personalized treatment for cancer patients

Challenge 10. To establish systematically knowledge framework for nanotoxicology to understand the long-term fate…

Challenge 11. To communicate with the public with respect to the safety/ethical concerns, and the tends to misconceive, magnify risk of NT (Nanomedicine)

Challenge 12. To develop standardization, regulatory framework, and policy to facilitate governance and approval (FDA), and sustainable development

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Today, we mainly focus on challenges related with *Challenges 10, 11 and 12*

Challenge 10. To establish systematically knowledge framework for nanotoxicology,

Challenge 11. To communicate with the public with respect to the safety/ethical concerns, and the tend to misconceive/magnify risk of NT (Nanomedicine)

Challenge 12. To develop standardization, regulatory framework, and policy to facilitate governance and approval (FDA), and sustainable development

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Challenge 10.

Systematically knowledge framework for nanotoxicology,

— The bases for safety standardization, risk assessment and governance regulations

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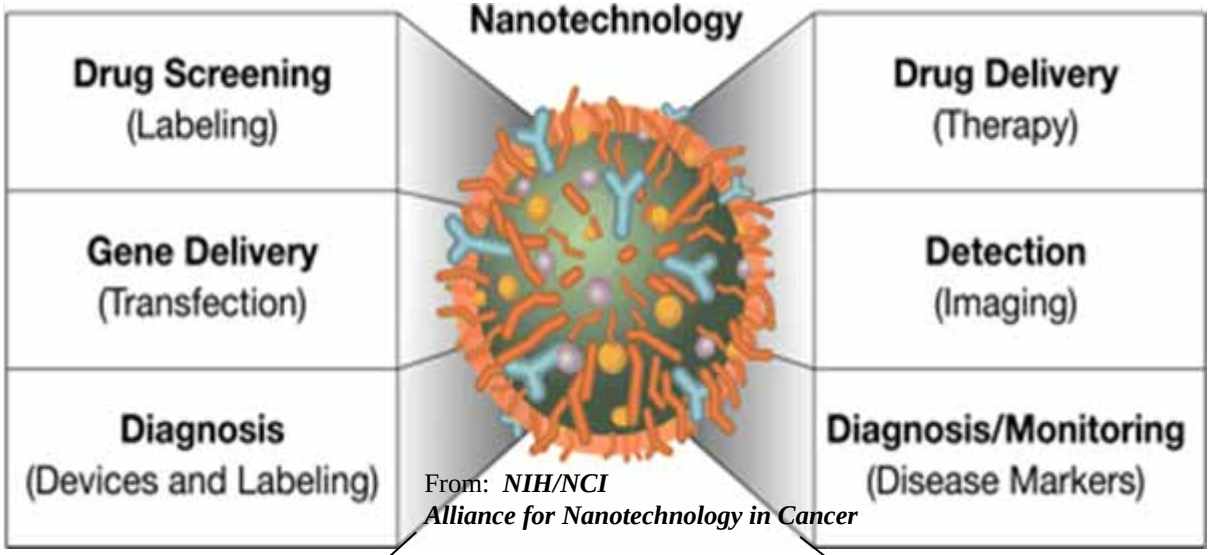
Nanomedicine & Cancer Nanotechnology



From: ***NIH/NCI***
Alliance for Nanotechnology in Cancer

Nanotechnology

Biomedical functions

Biological toxicity

The multifactors & complexity in risk evaluation of nanoscale materials

Bulk material	*Chemical composition, Dose, Exposure route*	
Nanomaterials	• **Mass concentration;** • **Reactivity;** • **Stability;** • **Solubility;** • **Morphology;** (crystalline or amorphous); • **Physical form;** (solid, aerosol, suspension, etc.); • **Purity / impurities;**	•**Quantum effects;** •**Nanostructure/shape;** •**Particles concentration;** •**Particle number;** •**Particle size/distribution;** •**Aggregation/agglomeration;** •**Surface chemistry;** •**Surface adsorption;** •**Surface Charge;** •**Self-assembly;** •……

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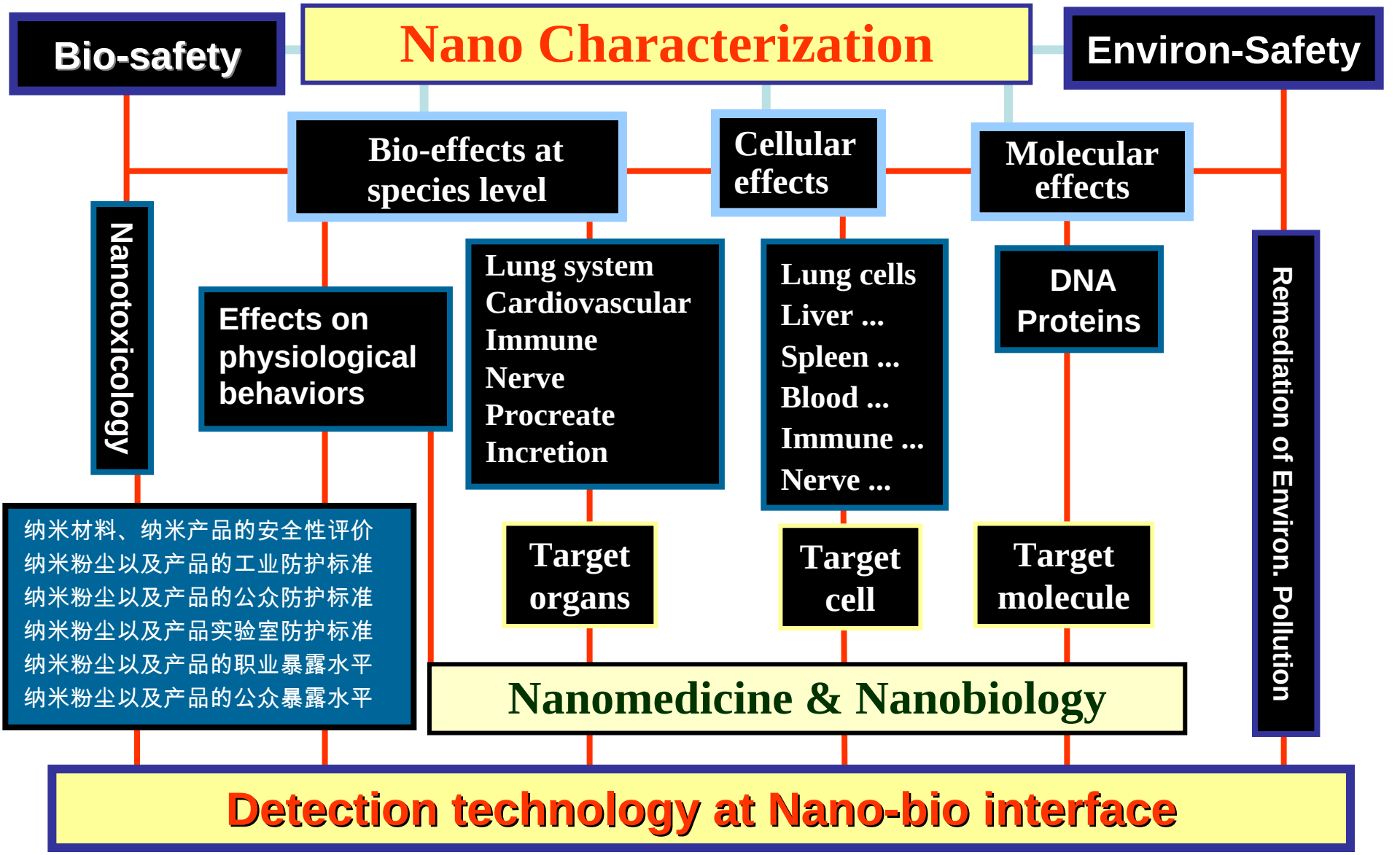
It needs Systematic Knowledge Framework for Nanotoxicology



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Efforts have been making to build Systematic Knowledge Framework for Nanotoxicology

From 2002-2010, we have explored some key factors that can dominate *nanotoxicity*

1. ***Dose-response relationship;***
2. ***Aggregation-response relationship;***
3. ***Nanosize-response relationship;***
4. ***Nanostructure-response relationship;***
5. ***Age-sensitive nanotoxicity;***
6. ***The way to regulate/eliminate nanotoxicity;***
7. ***Methodology: quantify nanoparticles in vivo;***

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@ *some journal papers for Nanotoxicology studies*

1. ***Toxicological Sciences,*** 107: 342-351, 2009.
2. ***Toxicological Sciences***, 103, 354-361, 2008.
3. ***Toxicology Letters***, 183, 72-80, 2008.
4. ***Toxicology Letters***, 175, 102-110, 2007.
5. ***Toxicology Letters,*** 170: 94-96, 2007.
6. ***Toxicology Letters,*** 168: 176-185, 2007.
7. ***Toxicology Letters***, 165, 112-120, 2006.
8. ***Toxicology Letters***, 163, 109-120, 2006.
9. ***Toxicology Letters***, 161, 115-123, 2006.
10. ***Toxicology***, 247, 102-111, 2008.
11. ***Toxicology,*** 254, 82- 90, 2008.
12. ***Environmental Science & Technology***, 39, 1378-1383, 2005.
13. ***Environmental Science & Technology***, 42, 8985-8992, 2008.
14. ***Toxicology and Applied Pharmacology,*** 230, 364-371, 2008.
15. ***Nature Nanotechnology****, 3, 191-192, 2008.*
16. ***Nano Letters*****,** 9(4), 1386-1394, 2009.
17. ***Nano Letters*****,** 5(10), 2050-2057, 2005,
18. ***Nanotoxicology*** *3(1), 1-5, 2008,*
19. ***Nanotechnology*** *19, 145102 (12pp), 2008.*
20. ***Nanotechnology*** *20: 225103 (9pp), 2009,*
21. ***Nanotechnology*** *20,415102 (10pp), 2009,* ***……***

From 2002-2010, about 60 papers for nanotoxicology, from CAS Nanosafety Lab

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CAS Nanosafety Lab: The nanotoxicology papers ranked at "Top 25 hottest papers" of toxicology field (Data from Science Direct Website)

2005, 4th quarter, 1 paper in Top 25, Ranking: 20,

2006, 1st quarter, 2 paper in Top 25, Ranking: 8, 14,

2006, 2nd quarter, 1 paper in Top 25, Ranking: 3,

2006, 3rd quarter, 1 paper in Top 25, Ranking: 3,

2006, 4th quarter, 2 paper in Top 25, Ranking: 5, 12,

2007, 1st quarter, 2 paper in Top 25, Ranking: 3, 23,

2007, 2nd quarter, 2 paper in Top 25, Ranking: 5, 12,

2007, 3rd quarter, 2 paper in Top 25, Ranking: 8, 18,

2007, 4th quarter, 3 paper in Top 25, Ranking: 10, 15, 22,

2008, 1st quarter, 3 paper in Top 25, Ranking: 13, 14, 15,

2008, 2nd quarter, 4 paper in Top 25, Ranking: 12, 18, 20, 21,

2008, 3rd quarter, 2 paper in Top 25, Ranking: 5, 8,

2008, 4th quarter, 2 paper in Top 25, Ranking: 6, 10,

2009, 1st quarter, 2 paper in Top 25, Ranking: 19, 20,

2009, 3rd quarter, 2 paper in Top 25, Ranking: 15, 24,

2009, 4th quarter, 2 paper in Top 25, Ranking: 21, 22,

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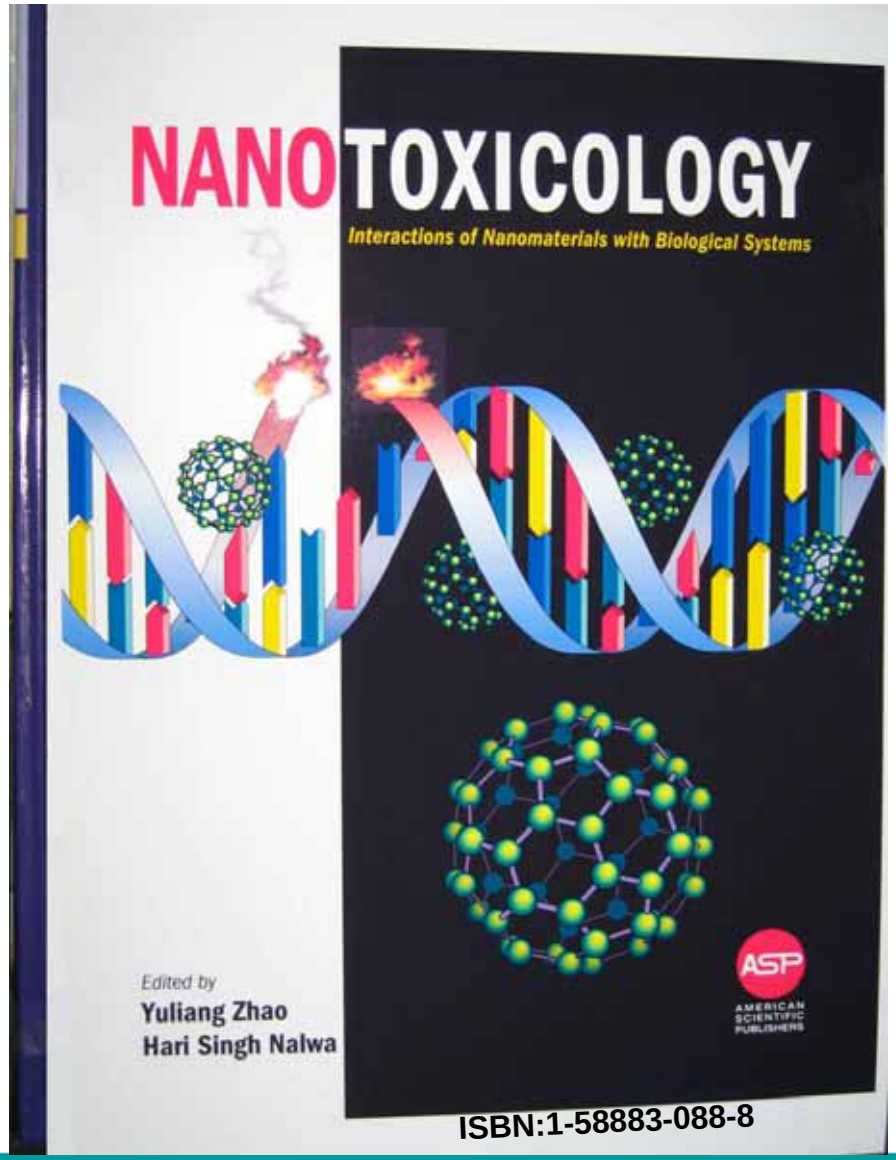
Efforts have been making to build Systematic Knowledge Framework for Nanotoxicology

Nanotoxicology
Yuliang Zhao
S.H. Nalwa edited

American Scientific Publishers
California, LA, USA, 2007



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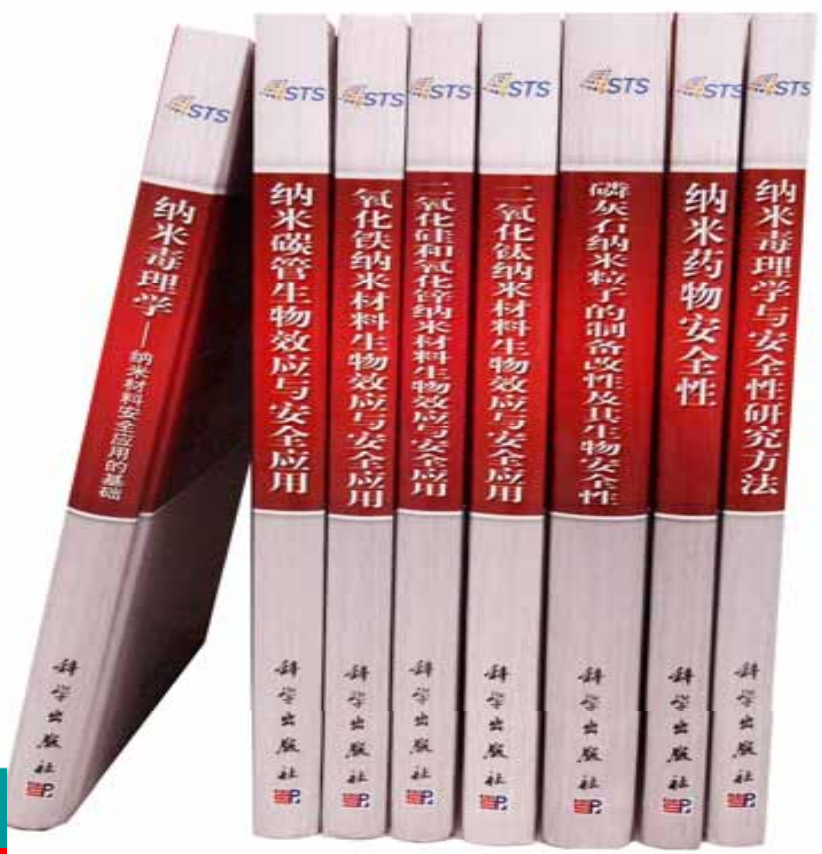
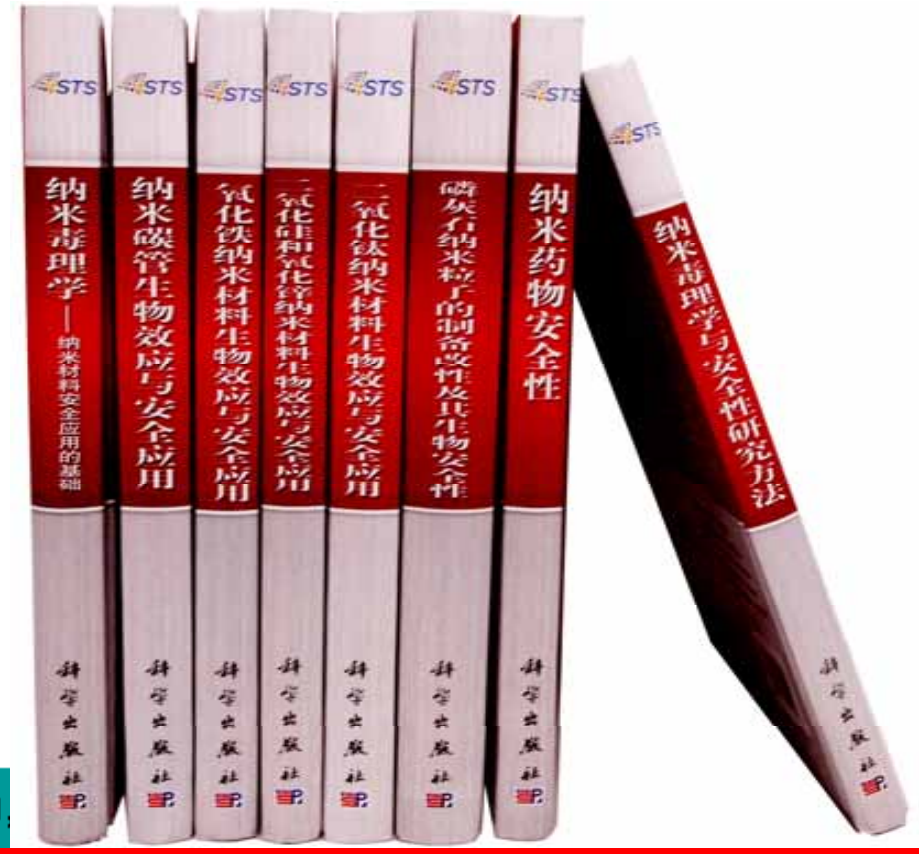
1。Nanotoxicology: The Basic Knowledge for Safe Uses of Nanomaterials
2. Safe Uses of Nanomedicine
3. Safe Use of Fullerene Nanomaterials
4. Safe Uses of Carbon Nanotube Materials
5. Safe Uses of TiO2 Nanomaterials
6. Safe Uses of SiO2 & ZnO Nanomaterials
7. Safe Uses of Iron Oxide Nanomaterials
8. Safe Uses of Metal Nanomaterials
9. Safe Uses of Apatite Nanomaterials
10. Methodology for Nanotoxicology

10 Volumes
Nanosafety Series
Yuliang Zhao, edited

Science Press,
Beijing, China,
2009, & 2010





What's the implication?

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"Information Asymmetry"

associated with safety issues of NT

- **In fact, scientists have gained and known much more knowledge about toxicological effects of nanomaterials than that being conceived by the public**

→ the progress in nanotoxicology field is not really aware of and known by the public, governance/admin organizations, and even by the nanotechnology community.

→ Need translation study from basic research findings to applications in safety evaluation

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Challenge 11.

To communicate with the public with respect to the safety/ethical concerns, and the tend to misconceive, magnify the risk of nanotechnology *(→ Nanomedicine)*

Nanosafety is not a pure nature scientific issue only: more importantly, it is an esthetical and politic question.

"The public is deeply concerning about the direction our society is moving and the technological development that goes on". *(K. David & P. Thompson, 2008)*

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ISO/TC 229 N 213

Our ref.: JA

Date: 2007-03-15

Secretariat of ISO/TC 229
Nanotechnologies

Dear Member

I am writing to you to solicit your views on the accompanying letter, which the Secretary and I have recently received from the ETC Group in respect of their competition to design a "nano-hazard" symbol. As you will see, the winning designs have been "respectfully" submitted to us for our "careful consideration" and we are asked to let the organisation know how we "choose to proceed".

Clearly, until one or more specific "nano" hazards has been identified, i.e. hazards resulting from size reduction to the nanoscale as opposed to hazards that are present at other length scales and which are also present at the nanoscale, it would be quite inappropriate to consider offering any support for, or recognition of such a symbol. However, before responding to the ETC Group we would value members' comments so that we can provide a consensus view from the TC. In your response would you please indicate whether you feel there is a need to discuss this issue at the forthcoming plenary or whether you are content for the Secretary and me to prepare a suitable reply indicated our rejection of the symbol as unnecessary and potentially misleading.

If we do not hear from you before the specified deadline we shall assume that you are satisfied for us to take the action indicated.

With kind regards

Dr Peter Hatto
Chairman ISO/TC 229

"nano-hazard" symbols proposed by ETC

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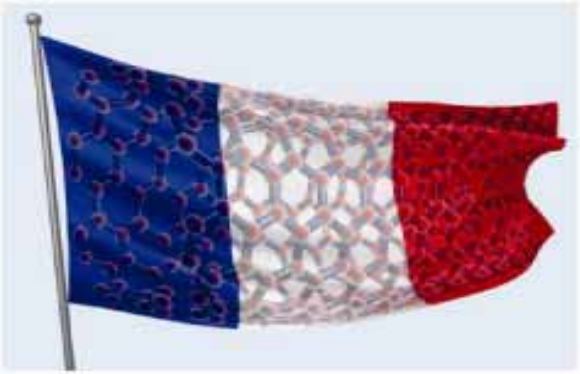
Chaos at French nanotech debates

22 January 2010



Protestors have caused the public to be banned from four debates on nanotechnology taking place across France. After Grenoble in December, and Rennes and Lyon in January, Marseilles saw the local debate organised by the Special Commission for Public Debate (CPDP) shut down by protestors on Tuesday. They clapped, whistled, shouted, threw paper balls, and raised banners with slogans such as 'Nano, it's not green, it's totalitarian'.

Although earlier debates had seen these protests questioning the legitimacy of the debates, organisers attempted discussion for more than thirty minutes before retreating to a private room to webcast the debate and interact with the public through the page's forum.

In addition to discussing nanotechnology with an audience of the general public, panellists from scientific, health, and environmental organisations planned to debate topics related to nanotechnologies. Nine other debates have successfully been held in other cities since October of last year.

France's public debates on nanotechnology have been disrupted by protesters

If the Parts and Labour organisation of Grenoble is not directly organising the protests, it certainly appears to be encouraging them through its website and a second nanotech-focused site. The organisation declined to comment when contacted by Chemistry World.

Both websites host articles which attempt to discredit the debates on grounds of funding, from the French Government, and the credibility of the independent panellists. The criticism was enough for the CPDP to post a letter on the debates' website in November, defending debate participants against accusations that they were government-controlled, through money or affiliation, rather than independent voices.

Marc Sentis, director of theLasers, Plasmas and Photonic Processes laboratory in Marseilles and one of Tuesday's panellists, says he decided to get involved with the debates in part because nuclear facilities were never the subject of such public discourse. 'I am 52, so I remember very well as a student, there was no possibility to debate about this important question,' he recalls. 'I didn't go to try to convince people. I still have to have some input [from the public] to know what is good or not.'

Sentis says that he understands to an extent the protesters' belief that 'everything is decided,' but says that in a democracy if you don't go and try to debate the issues, there is little chance of change.

The decision by one of the environmental groups due to take part in the debate to pull out on 13 January added a sense of legitimacy to the protesters' claim that the debates are 'phony' and 'antidemocratic'. According to Marie-Christine Gamberini of Friends of the Earth, the important questions on nanotechnology aren't being posed. The organisation lists nanoparticle toxicity, identification nanotechnologies that encroach on private life, and nanotechnologies for war as issues that need to be addressed.

Tuesday's debate, however, included three panellists from defence backgrounds and one from toxicology, suggesting that these topics are being considered.

In the web forum for Tuesday's webcast one contributor, Paul Cuivre of Paris, wrote that although many decisions had doubtless been made already, a public debate is still worthwhile. 'When I see the attitude of some immature individuals [.] who succeeded at perturbing the debate this evening, I ask myself questions about the future of participative democracy in France.'

Kate McAlpine

"Asymmetric Information"
Associated with
nanosafety issues

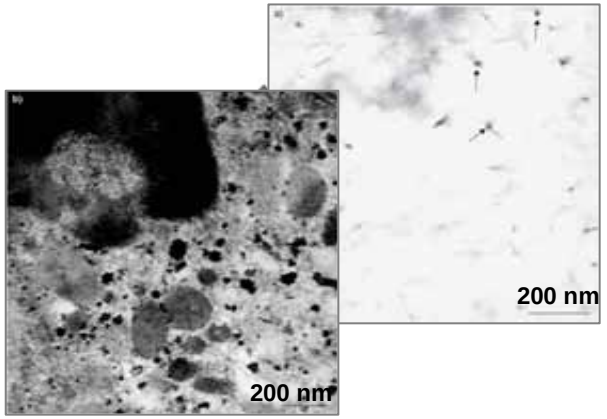
Public Debated on Nanotechnology

Accident

北京朝阳医院：喷涂纳米产品的车间工人死亡事件

Eur Respir J 2009; 34: 559–567
DOI: 10.1183/09031936.00178308

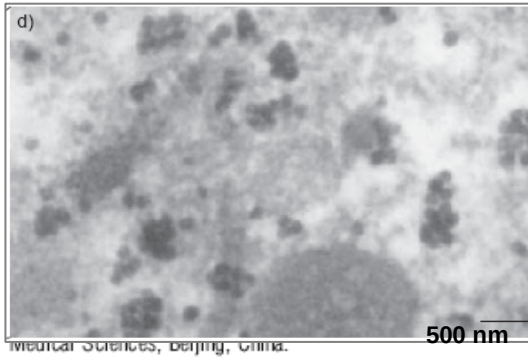
喷涂含TiO2纳米颗粒涂料的（18-47岁）工人死亡 ！



Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma

coating mixture of polyacrylic ester

Y. Song*, X. Li# and X. Du*



ABSTRACT: Nano materials generate great benefits as well as new potential risks. Animal studies and *in vitro* experiments show that nanoparticles can result in lung damage and other toxicity, but no reports on the clinical toxicity in humans due to nanoparticles have yet been made.

The present study aimed to examine the relationship between a group of workers' presenting with mysterious symptomatic findings and their nanoparticle exposure.

Seven young female workers (aged 18–47 yrs), exposed to nanoparticles for 5–13 months, all with shortness of breath and pleural effusions were admitted to hospital. Immunological tests, examinations of bacteriology, virology and tumour markers, bronchoscopy, internal thoracoscopy and video-assisted thoracic surgery were performed. Surveys of the workplace, clinical observations and examinations of the patients were conducted.

Polyacrylate, consisting of nanoparticles, was confirmed in the workplace. Pathological examinations of patients' lung tissue displayed nonspecific pulmonary inflammation, pulmonary fibrosis and foreign-body granulomas of pleura. Using transmission electron microscopy, nanoparticles were observed to lodge in the cytoplasm and caryoplasm of pulmonary epithelial and mesothelial cells, but are also located in the chest fluid. These cases arouse concern that long-term exposure to some nanoparticles without protective measures may be related to serious damage to human lungs.

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Nature
Science
Nature Materials
Nature Nanotech
ACS, RSC
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Nanoparticle safety in doubt

Claims that seven Chinese factory workers developed severe lung damage from inhaling nanoparticles are stoking the debate over the environmental-health effects of nanotechnology.

A paper published in the *European Respiratory Journal* claims to be the first to document cases of ill health caused by nanoparticles in humans (Y. Song, X. Li and X. Du *Eur. Respir. J.* 34, 559–567; 2009). Other experts are sceptical as to whether nanoparticles are actually to blame, but the paper has triggered lively discussions.

"The study raises the bar for doing appropriate research as fast as possible to find out where the dangers might lie when working with nanomaterials," says Andrew Maynard, a nanotechnology expert at the Woodrow Wilson International Center for Scholars in Washington DC.

The study describes seven women, aged 18–47 years, who worked in an unidentified printing factory in China; two of them later died. They all had pleural granulomas — ball-like collections of immune cells in the lining of the lung that form when the immune system is unable to remove a foreign body. They also had excessive, discoloured fluid in the lung lining. Particles around 30 nanometres in diameter were found in lung fluid and tissue.

The study says that the symptoms were caused by inhaling fumes produced

Could nanoparticles cause some lung damage?

full of nanoparticles".

Maynard says the symptoms seen in the patients are "similar" to those seen in animals exposed to nanoparticles. He adds that damage to the areas surrounding the lungs suggests that larger particles are not to blame, as these tend to be constrained within the lungs. But because the study does not identify what nanoparticles were involved or their concentration, he says, "we can't say what the link is or if there are other exacerbating circumstances".

Ken Donaldson, a respiratory toxicologist at the University of Edinburgh, UK, doubts that nanoparticles

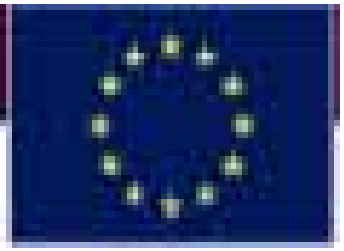
"We can't say what the link is or if there are other exacerbating circumstances."

Donaldson says that the plastic material the patients worked with is the more likely culprit — as it would have been highly toxic at the levels they were probably exposed to given the size of the room they worked in and its lack of ventilation.

Anthony Seaton, an emeritus professor in environmental and occupational medicine at the University of Aberdeen, UK, agrees that the study does not pin down nanoparticles as the cause of the ill health. Rather than an insight into the toxicology of nanoparticles, he says, the study is an example of a "total failure in health and safety procedures".

Natasha Gilbert

TOWARDS A STRATEGIC NANOTECHNOLOGY ACTION PLAN 2010-2015



May, 19, 2010

MAIN CONCLUSIONS

This public consultation on the needs and policies of nanotechnology over the next few years, as perceived by experts and the general public, was open from 18 December 2009 to 19 February 2010. More than 700 responses were received from the general public, individual researchers, research organisations, industry, public authorities and NGOs. The main conclusions are:

- Both experts and the general public see many benefits in nanotechnologies, as well as potential risks.
- More than 80% of respondents have either high or reasonable expectations of nanotechnologies in general.
- Some areas are seen as more promising than others, with regard to their expected benefits and potential risks. There was a sharp difference of opinions between experts and the general public, as well as among different nanotechnology applications.
- ICT and energy are seen as the areas of application where the benefits far outweigh any potential risks.
- Applications in healthcare are universally seen as very promising, but there is a strong perception of potential risks.
- Applications in aerospace, construction, sustainable chemistry, security and environment are seen as areas that would bring high benefits.
- Applications in agriculture, food and household items are regarded with more scepticism, although potential benefits in these areas were also identified by many respondents.
- The major concerns regarding policy centre on the safety of nanomaterials and their regulation. Generally, more action is expected to ensure safety.
- Another major concern, primarily raised by industry, is the rate of innovation in Europe and the risk that Europe may fall behind in the exploitation of its scientific base in nanotechnology.
- There is overwhelming demand for an inventory of the types and uses of nanomaterials that would include safety aspects. Demand is also high for requirements to ensure that adequate information is provided on consumer products.
- There is a good or very good perception of EU governance related to nanotechnologies in terms of stakeholder consultation and setting research priorities. All other areas did poorly.
- EU documentation and activities related to research and research funding – and to a lesser extent the European Strategy and Action Plan (SAP) on nanosciences and nanotechnologies – seem to be well known and are often used. Conversely, the opinions of the European Group on Ethics (EGE) regarding nanomedicine are largely unknown.
- There is a perceived need to strengthen action in all areas of nanotechnology strategy pursued until now, from research and innovation to safety and outreach.

1. International Dialogue on Responsible Development of Nanotech.
2. UNEP: Expert Group for Environmental Health and Nanotech.

On one hand, the governance agencies need urgently to develop the *risk-regulatory framework and procedures*.

Lack of risk assessment procedure, lack of the safety evaluation method, lack of regulations, etc., they are becoming *most important reasons leading to the public to misconceive, magnify the risk of nanotechnology*

On the other hand, we need more information & dialogue with the public, to increase the public awareness and understanding……

"Fear of the Unknown" !!

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Challenge 12.

Standardization, regulatory framework, and policy to facilitate governance, approval (e.g., FDA), and sustainable development.

The standardization and regulation/governance can be powerful forces in promotion of public acceptance with respect to nanomedicine.

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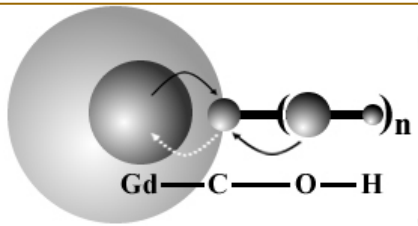
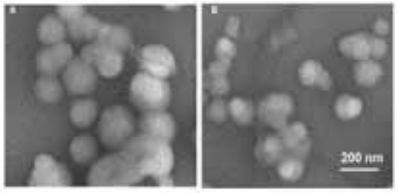
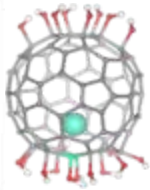
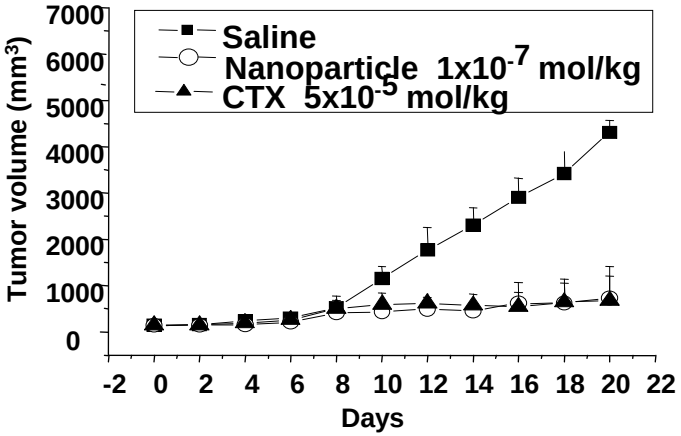
An Example

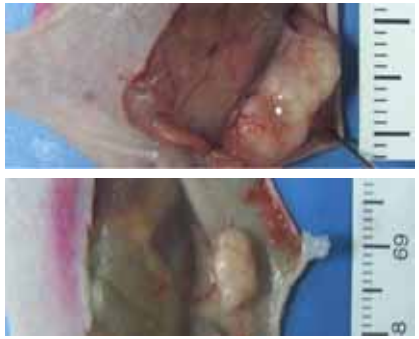
Lack of Confidence in regulatory system associated with Nanomedicine

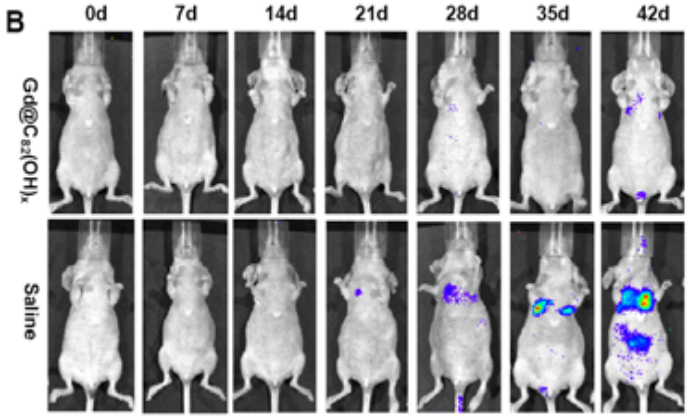


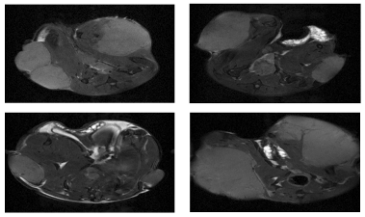


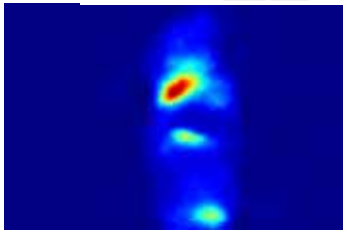




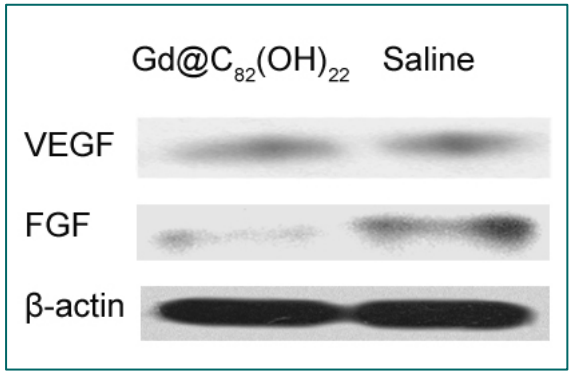


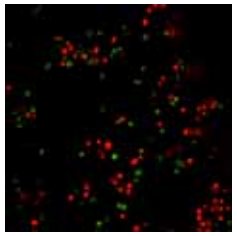


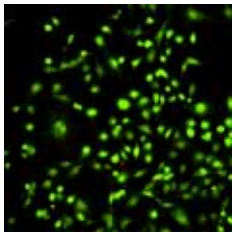


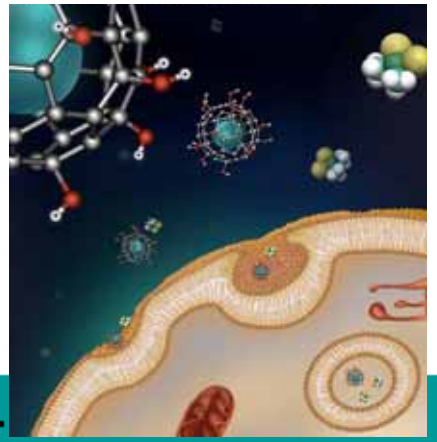


PNAS









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Lack of Confidence in regulatory system

PNAS, 107, 7449, 2010
Nano Letters, 4 (10), 1050, 2005
Advance Materials, 18,1458, 2006
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J. Phys. Chem. B 109(18), 87795, 2005.
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J. Phys. Chem. B 111(39), 6344, 2007,
Biochemical Pharmacology, 71(6), 872, 2006.
Molecular Pharmacology, 74(4), 1132, 2008.
Current Drug Metabolism, 9(10), 697, 2008.
……

High Efficacy & Low Toxic Chemotherapeutics with NPs

Though a huge amount of data, but when you are going to apply for approval for clinical trials, ……

Lack of confidence in the regulatory system associated with NT !

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A Strategic Action and its Implementation
—— China's Experiences

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China established Key Lab for Nanosafety Study

Opening Ceremony of joint Lab for Nanosafety in 2004

CAS leader

MOST leader

IHEP leader

NSFC leader

Opening Ceremony of CAS Key Lab for Nanosafety in 2008

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Staff at the CAS Key Lab for Nanosafety

	Staff				Posdoc, Students, etc					Total
	Resear-chers	Techni-cian	Admini-stration	Total staff	Postdoc	PhD student	Master student	Students from Univ.	Total student	
2009	29	8	2	39	8	33	19	26	87	126
Next 5 years	50	16	4	70	20	35	20	31	92	176

Directors: Prof. Yuliang Zhao

Co-director: Prof. Chen Wang

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Mission of CAS Nanosafety Lab

1. Particle properties; Methodology, Metrology

2. Hazards to Humans & the Environment

— The biological effects/safety issues, such as recognization, identification & quantification of hazards resulting from exposure to manufactured nanomaterials, &

— Behaviors of nanoparticles in air, water, other parts of the environment (including foods, and nanodrugs) and their health impacts.

— Accumulating experimental data on nanotoxicology and Nano-ecology database：

3. Recommendation of Regulatory Frameworks to government

— Draft out Regulatory Frameworks for research & industrial activities on NT

4. International Collaboration /linkage

— (Mutual recognization, Market admittance)

5. Safety Assessment for Nano-industries (enterprise)

— Develop Assessment method, procedure, identify toxicity class of nanomaterials……

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Network for nanosafety study in China

CAS Key Lab for Nanosafety

- Department of Chemical Biology, Peking University
- Medical School of Peking Univ.
- Chinese Academy of Medical Sciences
- Key Lab of Molecular Nanostructure & Nanotechnology, CAS
- Nan Jing University
- Shanghai Institute of Applied Physics, CAS
- Institute of Biological Physics, CAS
- State Key Lab. for Nuclear Magnetic Resonance and Atomic and Molecular Physics, CAS
- Shanghai University

…….. ***16 Institutions/Universities***

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Funding for Environment, Health and Safety Research in China

NSFC	Basic research: environmental effects of nanoparticles; nanoparticles in air; water purification; nanoscale processes in the environment; **Nanomedicine**
MOST	Toxicology of manufactured nanomaterials; Fate, transport, & transformation in human body; Human exposure and bioavailability; Transport & transformation of nanoparticles in the environment, exposure & risk analysis; **Nanomedicine**;
CAS	Physicochemical characteristics; Developing measurement tools, tests, and analytical methods ; Nanomaterials in the body, cell cultures, animal experiments, and laboratory use for diagnostic and research tools; **Nanomedicine**;
MoE	Potential toxicity of nanomaterials, Transport & transformation of nanoparticles in the environment, exposure & risk analysis; Health effects; **Nanomedicine**;
NCNST	Physicochemical characteristics & toxicological properties of nanomaterials; computational model that will predict toxic, salutary and biocompatible effects based on nanostructured features;
MoH	Toxicology of manufactured nanomaterials in working place; **Nanomedicine**;

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Efforts to reduce "Information Asymmetry" and its "side-effects" on sustainable NT ——China's experiences.

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To reduce "Information Asymmetry" and its "side-effects" on sustainable NT.

Encourage & help the public's awareness & understanding

To collect ideas from the public:

— their consideration of benefits of nanotechnologies in medical fields and consideration of ethical implications→ try to answer the questions

Publicize the Information on

— the research programmes, or strategies designed to address human health and/ or environmental safety aspects of nanomaterials

— any developments related to good practice documents

— the newly scientific understanding on EHS issues

— any risk assessment decisions

— the activities in *NANO* regulatory developments on health and environmental safety aspects of manufactured nanomaterials, Including nanomedicines, for example, recommendations, or discussions related to adapting existing regulatory systems or the drafting of laws/ regulations/ guidance

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1. Efforts to educate the public: High School Student

Facilitate public understanding and education to young people

NCNST and other research laboratory in CAS have OPEN DAY program for public, specially for university students, secondary school and primary school students.

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2. Efforts to educate the public: Graduate students

Nanosafety Summer Classes at Universities:

Tsinghua Univ., Peking Univ.,

Beijing Industry Univ., GUCAS, NCNST, ……

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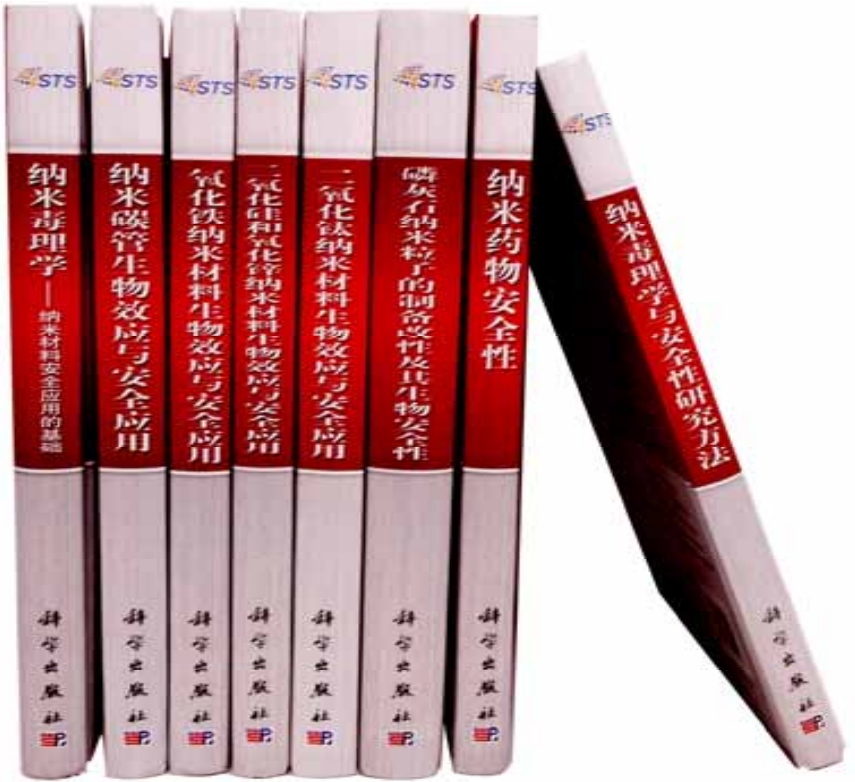
3. Efforts to educate the public: Systematize nanosafety knowledge to industry people

1. Nanotoxicology: The Basic Knowledge for Safe Uses of Nanomaterials
2. Safe Use of Nanomedicine
3. Safe Use of Fullerene Nanomaterials
4. Safe Use of Carbon Nanotube Materials
5. Safe Use of TiO_2 Nanomaterials
6. Safe Use of SiO_2 & ZnO Nanomaterials
7. Safe Use of Iron Oxide Nanomaterials
8. Safe Use of Metal Nanomaterials
9. Safe Use of Apatite Nanomaterials
10. Methodology for Nanotoxicology

10 Volumes
Nanosafety Series
Yuliang Zhao, edited

Science Press, Beijing, China, 2009, & 2010



National Library for Natural Sciences (CAS Library)

- Edit and publish documents for nanosafety issues quarterly.
- They are distributed to other libraries, governance organizations, related leaders, related laboratories.

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4. Efforts to translate the nanosafety knowledge to Nano people

National Nanosafety Conference

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5. Efforts to translate nanosafety knowledge to Medical People

In 2008, Establish "Research Center for Cancer Nanotechnology" with Tianjin Cancer Hospital

Chinese Academy of Sciences & Tianjin Cancer Hospital

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It is also important to build a rational *Nanosafety Culture*

What we can learn from many examples in our daily life:

The public attitude to

1) **Cigarette**
2) **Asbestos**
3) **Mobil phone radiation**
4) **Genetically modified food**
5) **Electricity**
6) **Nuclear power** **(subjectively, emotionally, false risk perceptions)**

Of cause, we should firstly study the hazard of nanoparticles, and know how to deal with them safely.

However, the current resource/investment for scientific investigation of nanotoxicology is quite limited.

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Need Global Harmonization/Collaboration for Nanosafety & Policy

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Need Global Actions for Nanosafety & Policy

Global Co-operation and Co-ordination

— to establish a global exchange platform: allowing all members to share their experiences and preoccupations with respect to nanosafety, and to identify opportunity for future co-operation & co-ordination.

— to establish the road map for nanosafety issues,

— to address the latest knowledge and research in order to find ways to collaborate and work together with the public to provide the best possible communication and information exchanges with the public,

— to establish practical strategies for policies of managing the risks of nanotechnology in medical sciences and industries.

to prevent from "Information Asymmetry" and its "side-effects".

→ ***to guarantee the safety for sustainable nanomedicine industry growth***

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Global Actions for Nanomedicine: Nanosafety & Policy

1. International Conference o Nanotechnology (ICNT2008, China)

2. China Co-ordinate with EU FP6, EU FP7 on nanosafety

3. China Co-ordinate with Canada Nanosafety Program, Natural Sciences and Engineering Research Council, Canada

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Global Actions for Nanomedicine: Nanosafety & Policy

2010, 02, 08-10, Global Congress on NanoEngineering for Medicine and Biology, Houston, USA

Chair: Mauro Ferrari

Ferrari Murad Curl Zhao

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Global Actions for Nanomedicine: Nanosafety & Policy

to prevent from "Information Asymmetry" and its "side-effects".

US-China Symposium on Cancer Nanotechnology & Nanomedicine (2008)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

http://www.nih.gov

National Center for Nanoscience and Technology of China
No. 11, First North Road
Zhongguangcun, Beijing
100080, P.R.China

Dear Drs. ChunLi Bai and YuLiang Zhao:

On behalf of the National Institutes of Health (NIH) and the Trans-NIH Nanotechnology Task Force, we are pleased to accept the gracious suggestion to co-sponsor the first Joint U.S.-China Symposium on Nanobiotechnology and Nanomedicine, in Beijing in October, 2008. The goal of this symposium will be to develop and apply nanotechnology to prevent, detect, diagnose and treat disease, and to consider the effect of exposure to nanomaterials on workers, the general public and the environment. We trust that this initial dialogue will comprise an important first step in sharing information, scientific brainstorming, and developing mutually productive collaborations and working relationships between Chinese and American scientists.

The NIH constitutes one of eight agencies that compose the Public Health Service (PHS) in the Department of Health and Human Services (DHHS), United States of America (USA). It is the primary Federal agency for conducting and supporting medical research, and as such, it provides leadership and financial support to researchers in every state in the U.S., and throughout the world.

ith our esteemed Chinese colleagues from the
emy of Medical Sciences, the National Science
arch universities and research institutes. We
ally inspiring meeting, and to collaboratively
in nanoscience.

Sincerely yours,

Elias A. Zerhouni, M.D.
Director, NIH

John E. Niederhuber, M.D.
Director, NCI

Samuel Wilson, M.D.
Acting Director, NIEHS

Global Actions for Nanomedicine: Nanosafety & Policy

Cancer Research, 2009, 69 (13), 5294-5295.

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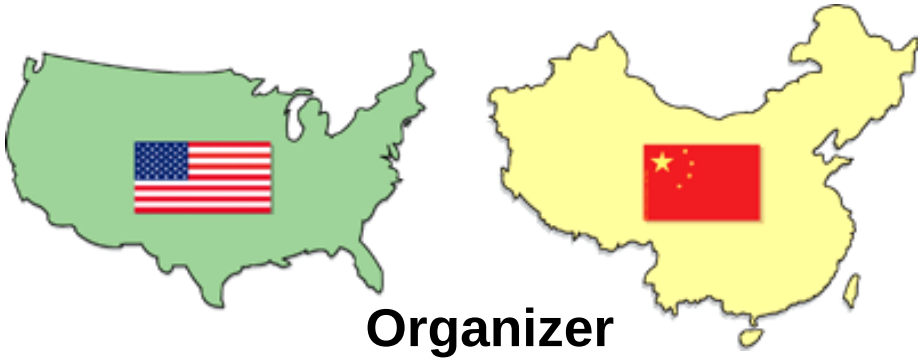
Global Actions for Nanomedicine: Nanosafety & Policy

The 2nd U.S.-China Symposium on Cancer Nanotechnology & Nanomedicine.

September 16-18, 2010, Washington, DC



Organizer

Dr. Piotr Grodzinski

Need Standardization

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Need Standardization — China`s experience

The China National Nanotechnology Standardization Technical Committee (SAC / TC279) was founded in April 1, 2005,
The current committee has a sub-committee and six working groups, covering all aspects of nanotechnology.

- **Secretariat**
- **Sub-committee for Nano-Materials**
- **Working groups of SPM**
- **Working groups of Nanofabrication**
- **Working groups of Nano-Indentation and Scratches**
- **Working groups of Measurement Technology**
- **Working groups of Health, Safety and Environment**
- **Shanghai Nanothecnology Working Groups**

Website of **SAC / TC279** (www.nano-standards.org.cn)

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Need Standardization — China`s experience

21 China Standards of nanotechnologies were published and implemented; About 40 China Standards of nanotechnologies are under development; three of them have been recommended and approved as work items of ISO, and are in the producing process.

National standard items already published and to be enforced

1. **20068672-T-491 General rules of instrumented nanoindentation test**
2. **20074426-T-491 Characterization of gold nanorods：UV-Vis-NIR absorption spectroscopy**
3. **20074433-T-491 Characterization of CdSe quantum dot nanocrystals UV-Vis absorption spectroscopy**
4. **20074434-T-491 Test method for hydrophobic contamination on glass by contact angle measurement**

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Need Standardization — China`s experience

Published and implemented China Standards of nanotechnologies:

1. **GB/T 19619-2004Terminology for nanomaterials**
2. **GB/T 13221-2004 Nanometer power-Determination of particle size distribution-Small angle X-ray scattering method(ISO/TS 13762:2001,MOD)**
3. **GB/T 19587-2004 Determination of the specific surface area of solids by gas adsorption using the BET method(ISO 9277:1995,NEQ)**
4. **GB/T 19588-2004 Nano-nickel powder**
5. **GB/T 19589-2004 Nano-zinc powder**
6. **GB/T 19590-2004 Nano-calcium carbonate**
7. **GB/T 19591-2004 Nano-titanium dioxide**
8. **GB/T 19627-2005 Particle size analysis-Photon correlation spectroscopy (ISO 13321:1996,IDT)**
9. **GB/T 15445.2-2006 Representation of results of particle size analysis—Part 2:Calculation of average particle sizes/diameters and moments from particle size distributions（ISO 9276 - 2：2001,IDT）**

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Need Standardization — China's experience

10. GB/T 15445.4-2006 Representation of results of particle size analysis—Part2:Characterization of a classification process（ISO 9276 - 4：2001,IDT）
11. GB/T 20307-2006 General rules for nanometer-scale length measurement by SEM
12. GB/T 20099-2006 Sample preparation dispersing procedures for powders in liquids
13. GB/T 21511.1-2008 Nano-apatite/polyamide composite.Part 1:
14. GB/T 21510-2008 Antimicrobial property detection methods for nano-inorganic materials
15. GB/T 21511.2-2008 Nano-apatite/polyamide composite.Part 2:Technology requirements
16. GB/Z 21738-2008 The methods for the determination of basic structure of one dimensional nano-material --High-resolution electron microscopy characterization
17. GB/T 21838.4-2008 Metallic materials.Instrumented indentation test for hardness and materials Parameters.Part 4:Test method for metallic and non-metallic coatings

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Standardizations — Global Collaborations

THE 7Th MEETING OF ISO/TC 229 HELD ON 21ST NOVEMBER 2008, SHANGHAI, PEOPLES' REPUBLIC OF CHINA

- **Need to establish a common roadmap linking the individual WG roadmaps. This work should be presented to the TC at the Seattle meeting in June 2009.**
- **Availability of online tools and training material for experts from a number of NSBs. The Chairman had requested members to share such tools for the benefit of the wider community of experts.**
- **Discussion about the use of the Livelink websites and reminder to members of the need to nominate experts to the different PGs informing the Secretary of such nomination and providing them with access to the relevant group website.**
- **The TC 229 programme of work is expanding rapidly and it needs to meet the needs of the Roadmap.**

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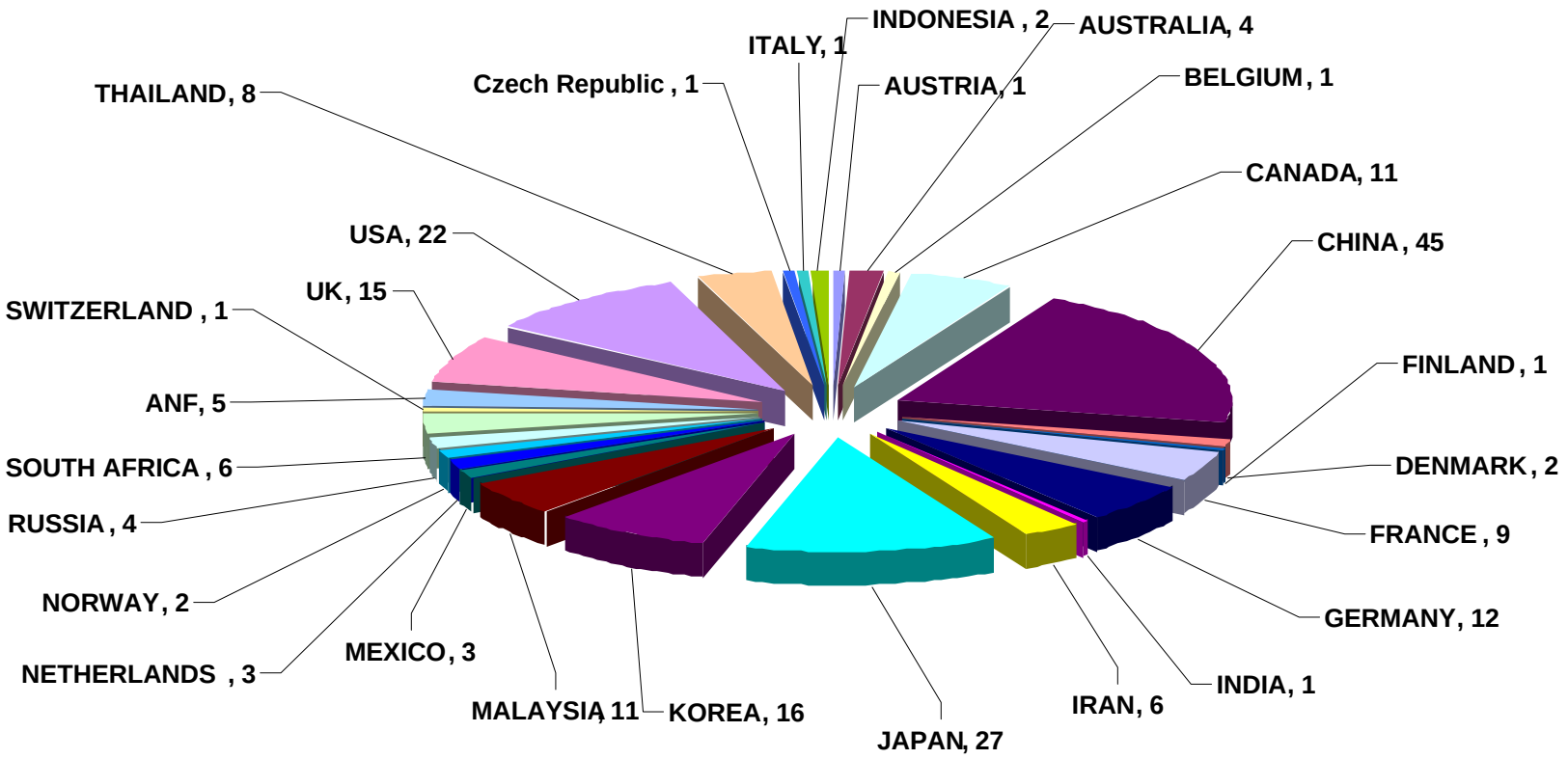
ISO/TC229 7th conference

Over 223 registered representatives attended the conference, 182 came from overseas: 26 countries and areas.



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Summary: Need Roadmap

Nanomedicine may be more acceptable to the people than other nanotechnology or nano-products incorporating nanomaterials, because patients have their own values to weigh up the gains and losses, if nanomedicines can provide solutions to the major human diseases, like cancer.

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Need A Roadmap

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Thank you

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