CAPACITY BUILDING IN SAFE NANOTECHNOLOGIES

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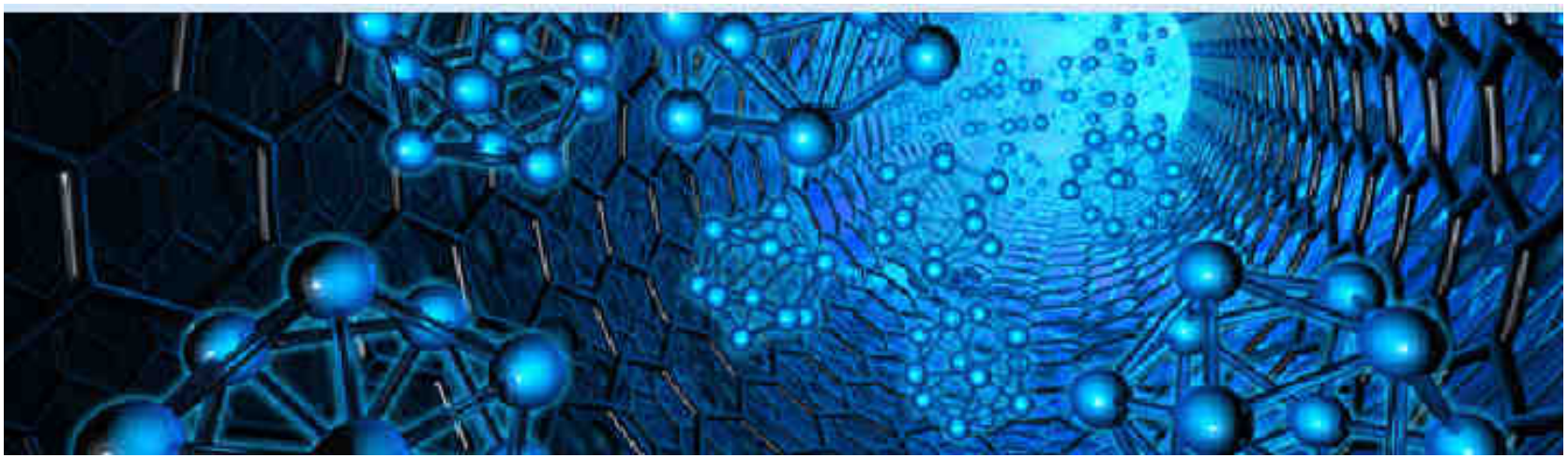

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SAFETY REQUIRENMENTS
what needs the nano-world?

- Different **solutions exist readily available on the market** for all safety aspects and levels. It is even possible to set-up adequate worker safety in a bioloical risk laboratory S4 (working with ex. Ebola)
- A **definition** what is needed for safe handling can´t be given upon the determination of a possible classification about health risk from ENPs.
- **Only suggestions can be given.** As long as no final assessment regarding toxicity is available, ENPs should be regarded as potentially toxic (worst case scenario).
- ENPs in compounds or agglomerated have to regarded separately as they tend to show different characteristics. (CNTs in ESD flooring etc.)

- Examples from existing controlled environments:

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CONTROLLED ENVIRONMENTS
what can be transferred to the nano-world?

- Cleanroom settings: Example life-science industries:
  GMP air cleanliness classifications acc. to EU-GMP Annex 1 Volume 4
- -> no nanoscale definitions (not necessary for sterile production? What about prions, viruses,…? Open topic!)

Cleanliness Class	Maximum permissible particle count per m^3 in a resting state		Maximum permissible particle count per m^3 in an operating state	
	> 0.5 µm	> 5 µm	> 0.5 µm	> 5 µm
A	3,520	20	3,520	20
B	3,520	29	352,000	2,900
C	352,000	2,900	3,520,000	29,000
D	3,520,000	29,000	Not fixed	Not fixed

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CONTROLLED ENVIRONMENTS
what can be transferred to the nano-world?

- Cleanroom settings: Example semiconductor industries:
  ISO air cleanliness classifications acc. to EN ISO 14644-1 (1999)
- -> definitions in the nanoscale down to 100 nm.

Regulatory				Limiting values of each air cleanliness class for differing particle sizes and reference volumes (acc. to ISO 14644-1)											
DIN EN ISO 14644-1	EU-GMP "at rest"	EU-GMP "in operation"	US Fed. Standard 209E*	0.1 µm		0.2 µm		0.3 µm		0.5 µm		1.0 µm		5.0 µm	
				per m³	per cbf	per m³	per cbf	per m³	per cbf	per m³	per cbf	per m³	per cbf	per m³	per cbf
1				10	0,3	2	0,1								
2				100	3	24	1	10	0,3	4	0,1				
3				1.000	30	237	7	102	3	35	1	8	0,2		
			1	1.240	35	265	8	106	3	35	1				
4				10.000	300	2.370	67	1.020	29	352	9,9	83	2		
			10	12.000	340	2.650	75	1.060	29	353	10				
5				100.000	2.833	23.700	671	10.200	289	3.520	100	832	24	29	0,8
	A	A								3.520	100			20	0,6
	B									3.520	100			29	0,8
			100			26.500	750	10.600	300	3.530	100				
6				1.000.000	28.329	237.000	671	102.000	2.890	35.200	997	8.320	235	293	8
			1.000							35.300	1.000			247	7
7										352.000	9.972	83.200	2.357	2.930	83

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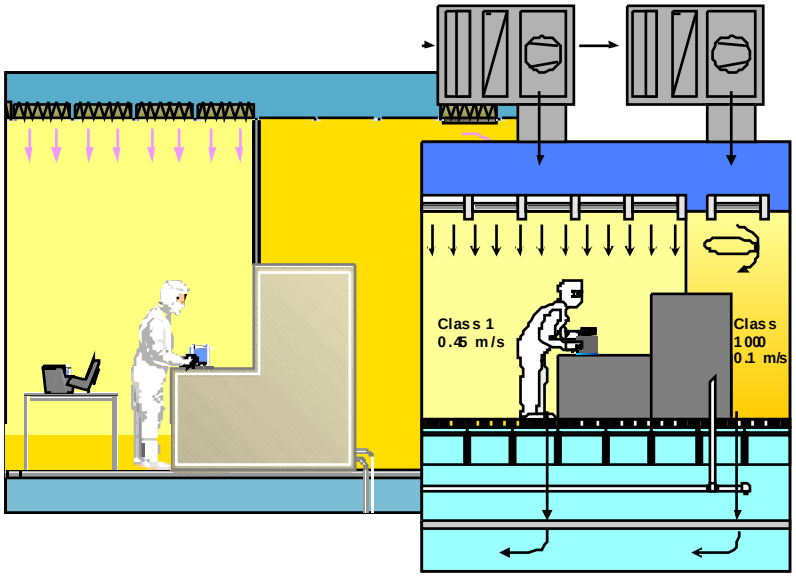
CONTROLLED ENVIRONMENTS
what can be transferred to the nano-world?

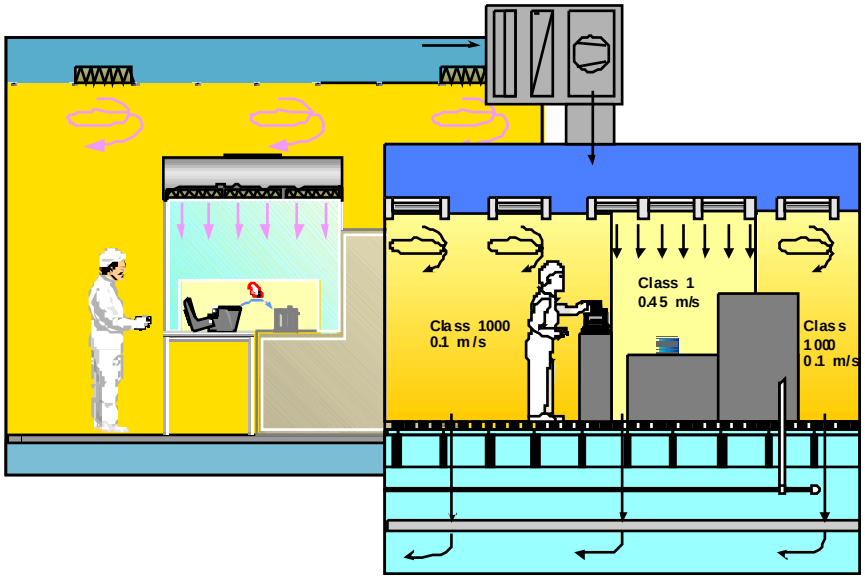
- Cleanroom settings: Example semiconductor industries

Equipment without mini-environment & "open cassette"



Tunnel-Type Cleanroom

Equipment with mini-environment & "FOUP"



SMIF-Type Cleanroom

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CONTROLLED ENVIRONMENTS
what can be transferred to the nano-world?

- **Mini-environments** used in **GMP class A** or biological safety labs **S3 or S4**: it is possible to set-up a production line with complete separation from the worker. Overscale? Depends on the handled product regarding its toxicity!

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CONTROLLED ENVIRONMENTS
Outcome

Following suggestions can be given:

- usage of a **restricted area barrier access system (RABS), a mini-environment or a glovebox** can be useful as precaution issue.
- Therefore, there is no need to install a complete cleanroom system.
- Possibly useful additional safety equipment: **emergency fume extractor** for the whole lab activated through a specially labelled emergency switch in the laboratory setting itself

Source: CDC, James Gathany, published at Wikipedia

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SAFETY EQUIPMENT FOR WORKERS
what can be transferred to the nano-world?

Gloves

- standard latex gloves are advisable to wear all the time in an ENP lab (see also actual R&D results)
- think of adequate disposal! (avoid cross-contamination, SOP for waste treatment)

Safety clothing

- wearing a lab-coat or cleanroom coat and protective eyewear should be mandatory in an ENP lab.
- The lab-coats have to be kept inside the ENP lab and stored in a adjacted dressing room.
- the coat cleaning has to be performed in a controlled manner (SOP for cleaning procedures).

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SAFETY EQUIPMENT FOR WORKERS
what can be transferred to the nano-world?

Personnel breathing protection

- Classification acc. to EN 149
- Recommendation for work related with ENPs: **FFP3 face masks**. This is the most inportant personnel protection item in an ENP lab!

Class	Filter penetration limit (at 95 l/min air flow)	Inward leakage
FFP1	Filters at least 80 % of airborne particles	<22 %
FFP2	Filters at least 94 % of airborne particles	<8 %
FFP3	Filters at least 99 % of airborne particles	<2 %

Source: 3M

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WORKPLACE AND WORKFLOW ORGANIZATION

- **Reduce handling steps** and avoid unnecessary double handling
- **Keep the potentially risky substances as far away as possible** from human workers
- If handling ENPs in an open process, **use fume extractors, minienvironments or RABS systems** as far as possible
- A logical workflow setup from **clean to dirty** areas minimizes possible ENP cross contamination
- **Label all containers** filled with ENP-substances clearly with substance, filling date and name of the worker:

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WORKPLACE AND WORKFLOW ORGANIZATION

- **Storage and disposal areas should be labeled.**
- The whole ENP lab area should be **restricted access** only with appropriate warning signs at the entrance doors for “nanorisk” or other labeling
- Basic and mostly mandatory lab requirements need to be addressed as well:
  - Emergency shower?
  - Eye cleaning devices?
  - First aid kit?
  - Evacuation plan?
  - Alert plan?
  - Regularly training of personnel?
  - Lab area and workers visible from outside?
  - Emergency phone numbers?
  - Remind that an ENP lab is mainly an extension to a standard chemical lab!
- Single usage disposable cleaning cloths and mops should be preferred.

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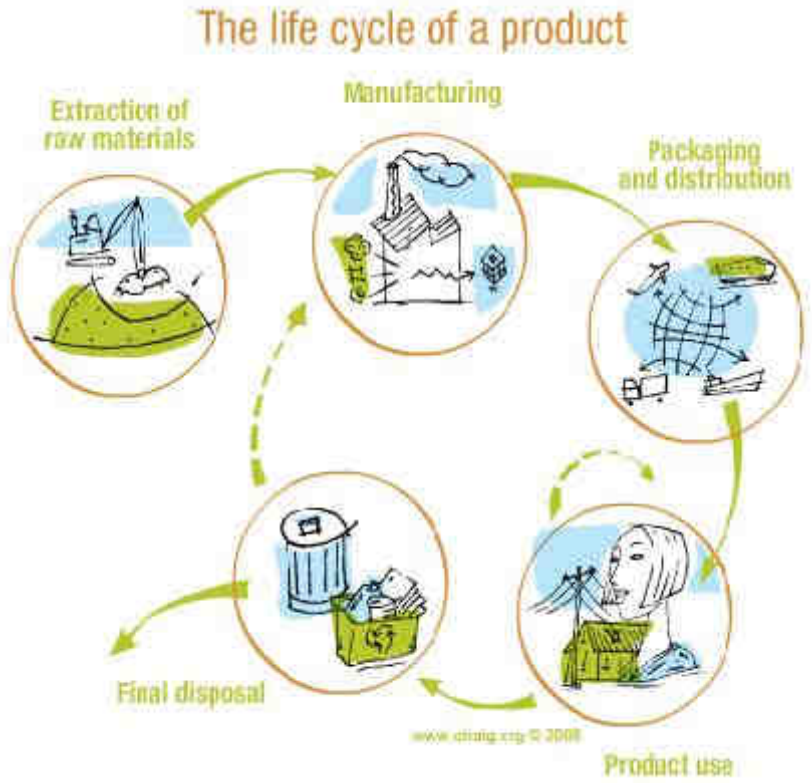
WASTE TREATMENT
an open topic about the life cycle of ENPs!

- How should lab or industrial wastewater with possible ENP contamination be treated?
- How should the exhaust air from air conditioning systems and fume extractors be filtered?
- Which filter system has to be used to retrain the focused ENPs?
- What about the whole life cycle of a product containing ENPs?
- What happens during thermal treatment in a waste disposal plant?



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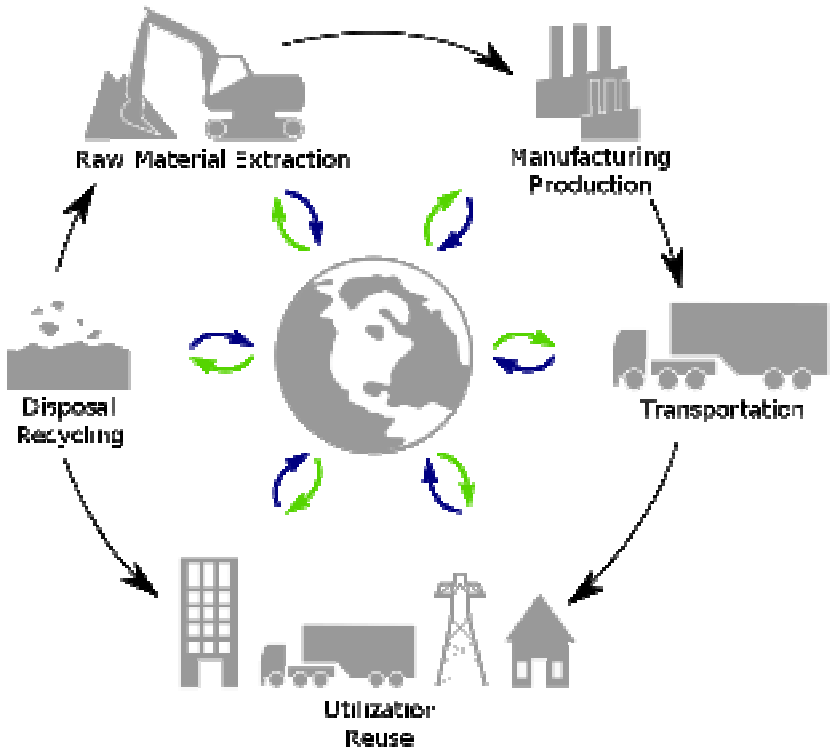
WASTE TREATMENT
an open topic about the life cycle of ENPs!

- How will ENPs introduced in the environment behave after release? Will accumulation or even bioaccumulation occur inside microorganisms or higher living organisms?
- Which other organisms can be negatively influenced from ENP introduction into the environment (plants, vertebrates, insects,…)?
- Will biodegradation or chemical degradation occur to some ENP groups, like carbon nano tubes (CNT)?



Source: Wikipedia

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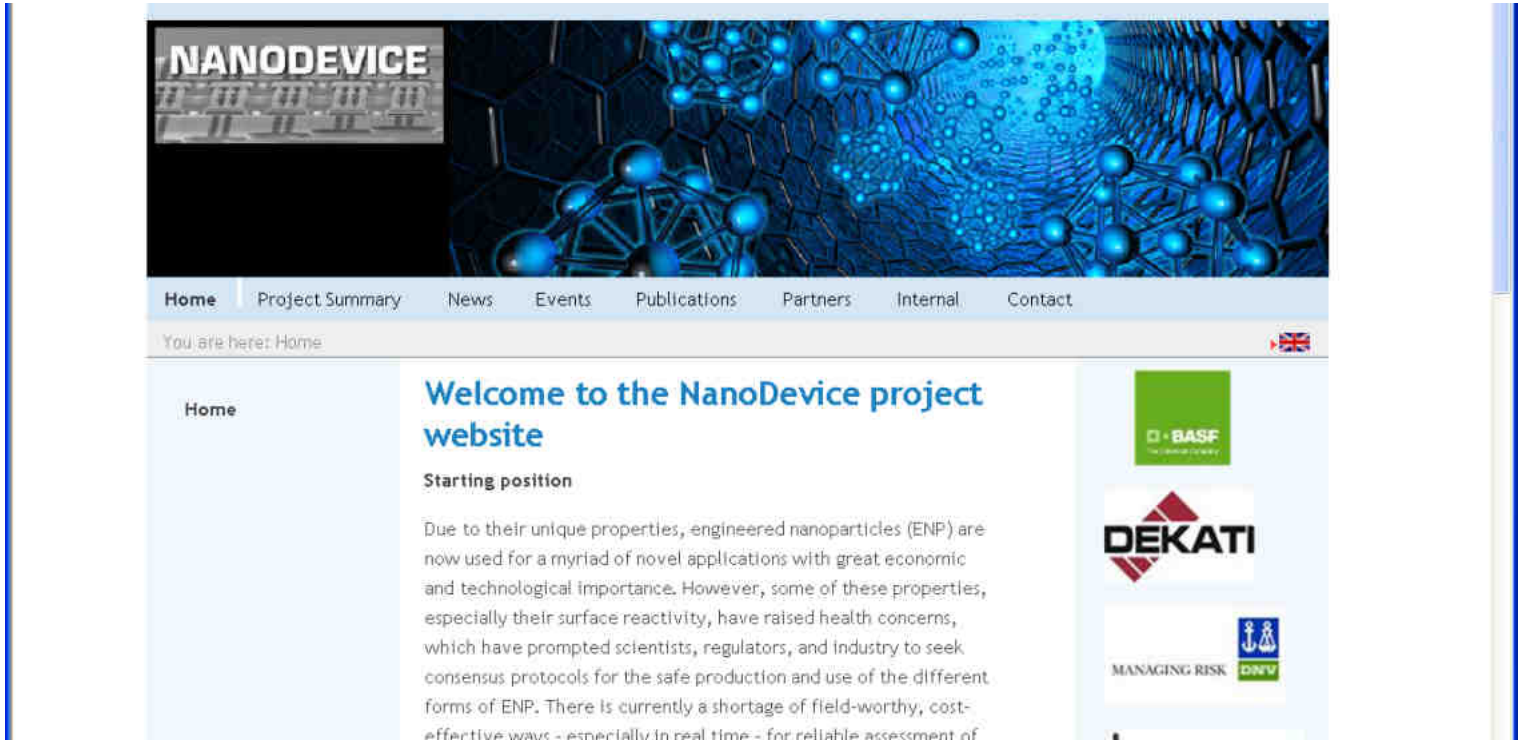
GET AWARE OF THE POTENTIAL RISKS!
Dissemination activities

- Public project homepage, see **www.nano-device.eu**



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GET AWARE OF THE POTENTIAL RISKS!
Dissemination activities

- NanoDevice project network with 26 partners covering whole Europe
- A handbook will be published during the NanoDevice project
- ENP risk subject should be included in lectures and seminars at universities
- Talks at conferences and workshops
  (next at the INRS Occupational Health Conference 2011, see www.inrs.fr)

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GET AWARE OF THE POTENTIAL RISKS!
Dissemination activities

- A possible design of an “nanorisk” sign is already in discussion, see ETC group (2007). These are the three winners from a public enquiry:

ETC Group (2007): Winners of Nano-Hazard Symbol Contest Announced at World Social Forum, Nairobi,Kenya, see http://www.etcgroup.org/upload/publication/604/02/ wsffinalcontestjan24_07.pdf, accessed november, 2010.

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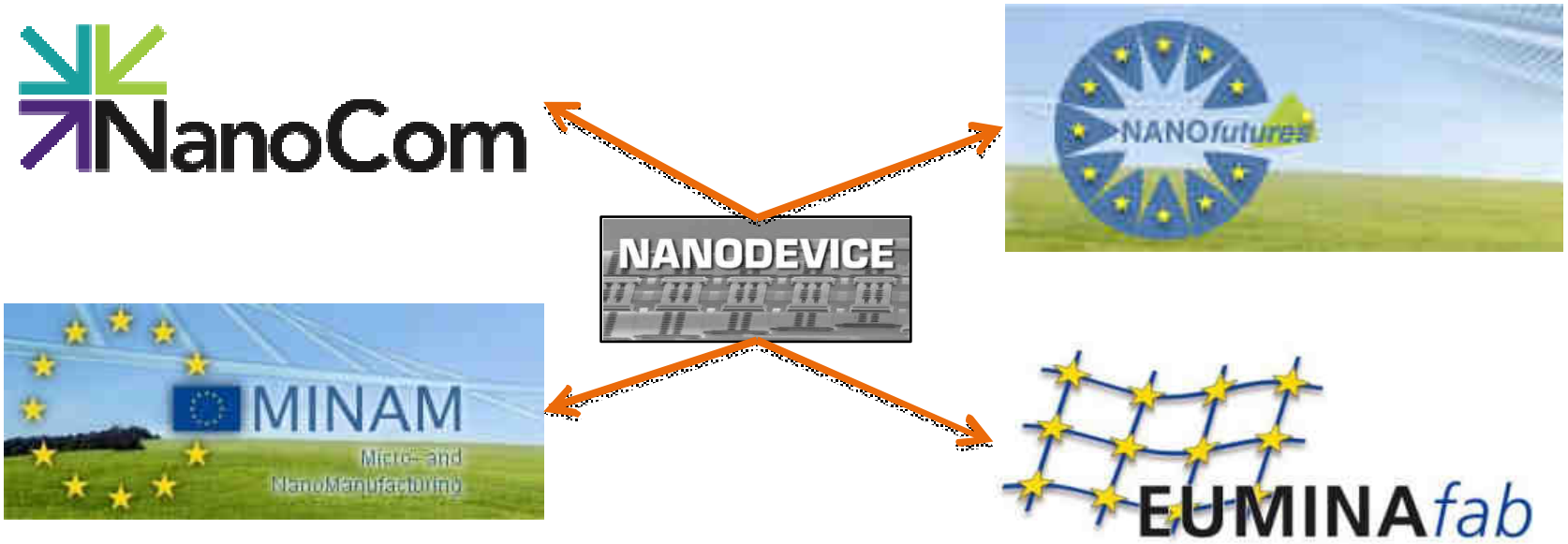
GET AWARE OF THE POTENTIAL RISKS!
Dissemination activities

- Planned **joint workshop with other EU FP7 coordinating action projects** in spring 2011 at the Fraunhofer IPA, Stuttgart, Germany
- **NANOfutures** organizes two Technology Transfer events every year, first planned May 2011 with planned contribution from NanoDevice



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QUESTIONS? CONTACT

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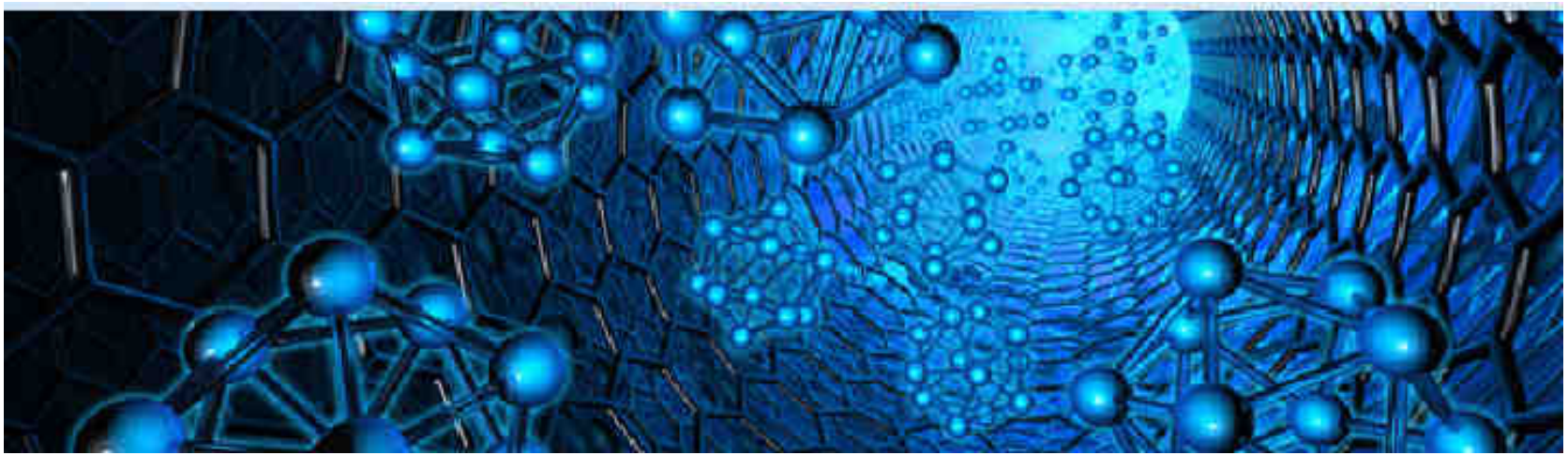

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