A common European approach to the regulatory testing of nanomaterials

NANoREG

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SEVENTH FRAMEWORK PROGRAMME

Goals of Regulation of Technology

- Restrain technological risks
- Ensure occupational health and safety at the workplace
- Stimulate innovation and foster competitiveness (support of R&D and standardization)
- Direct technological change
- Remedy market failures, introduce incentives into markets to “internalize the externalities”
- Provide effective consumer protection
- Support protection of the environment
- Inform users and the general public, address public concern and build trust

Where did we start and where are we now?

<u>Improvement</u>
accompany new technology with safety research

<u>Disadvantage</u>
emphasis scientific approach: getting lost in details

trying to solve hitherto unsolved/unsolvable problems
in chemical risk assessment

Regulatory reality:

chemicals‘ legislation / occupational safety

- we always have to deal with data gaps
- we have to cover all marketed materials

Strategy

- focus on putatively relevant health hazards
- are there ways to group nanomaterials
- according to same mode of toxic action?

Which nanomaterials pose particular concern?

- particulate nanomaterial dusts:

  relevance of inhalation exposure (respirable dust)

+

- high persistence in biological systems

- *not covered : medical applications:*
  - *materials are generally different due to design (e.g. solid lipids)*
  - *different definition (primary particle diameter up to 1000 nm)*

Nano safety: state of the art

many relevant questions are answered

risk assessment strategies can be developed

as always and for every chemical:
there will be open questions left!

It is respirable (nano-)dust that matters most!

Summary I

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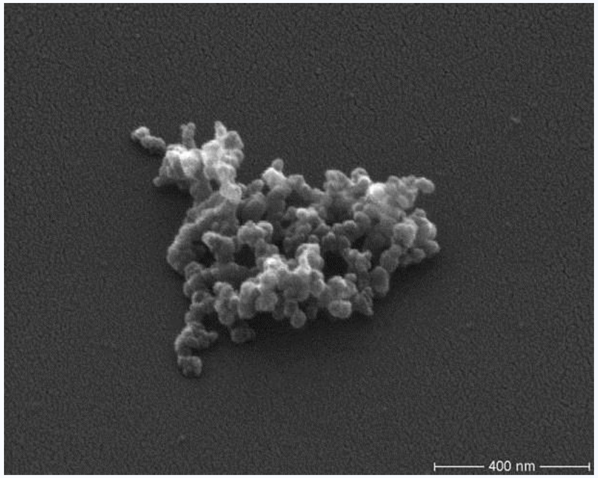
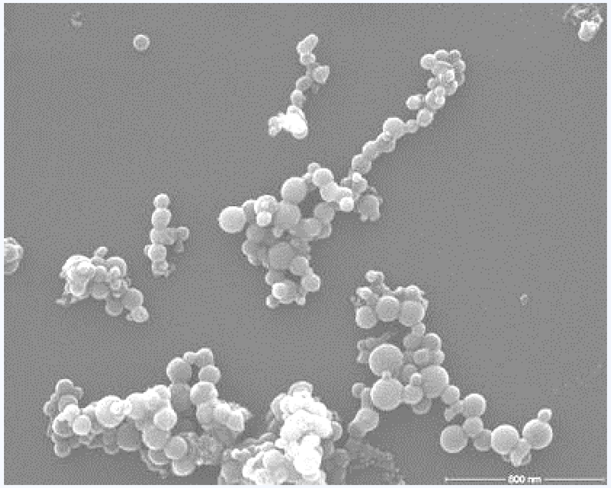
nanomaterial health hazards
can be described by known modes of toxic action

⇒ methods for the evaluation of possible effects of nanomaterials are available



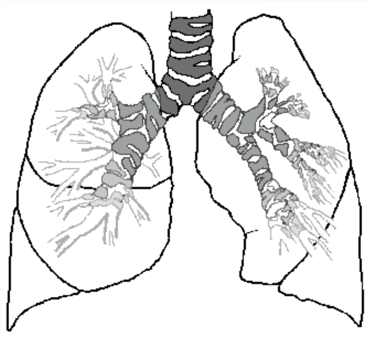


There is currently no evidence for
a new & specific nanomaterial toxicology.

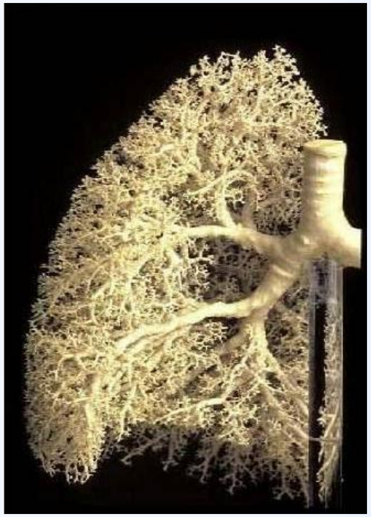
Pics: BAuA, Plitzko

Summary II

The relevant toxic effects of the major nanomaterials
are covered by the current knowledge in dust toxicology



target organ: lung
(inhalation exposure
is relevant
exposure pathway)



→ effects are known:

chronic inhalation of respirable dust (work place!):
inflammation and putative carcinogenicity

nanotoxicology

scientist	vs regulator
I need positive finding to publish	I want to see your negative data
I publish a positive finding	adversity? what does it mean for real life?
I saw a particle in a cell	I need quantitative and representative data
I adjusted my experimental protocol till I found a positive effect	Why didn‘t you use the validated standard protocol? These findings do not help me.
I found something with my nanostuff	Why didn‘t you test bulk in parallel?

Four Regulatory Discourses

Currently, 4 interwoven discourses (about different subjects):

1. Unknown properties of nanoscale materials (nanoparticles) and their impact on humans and the environment
2. NT as another representative of ‘risk technologies’ in general debates about science and technology in society
3. Risks of new nanotechnologies (3rd/4th Generation NT, Molecular NT)
4. Implications of technologies enabled by NT (e.g. medical technologies: bioethics, neuroethics; IT: privacy, ...)

4 generations

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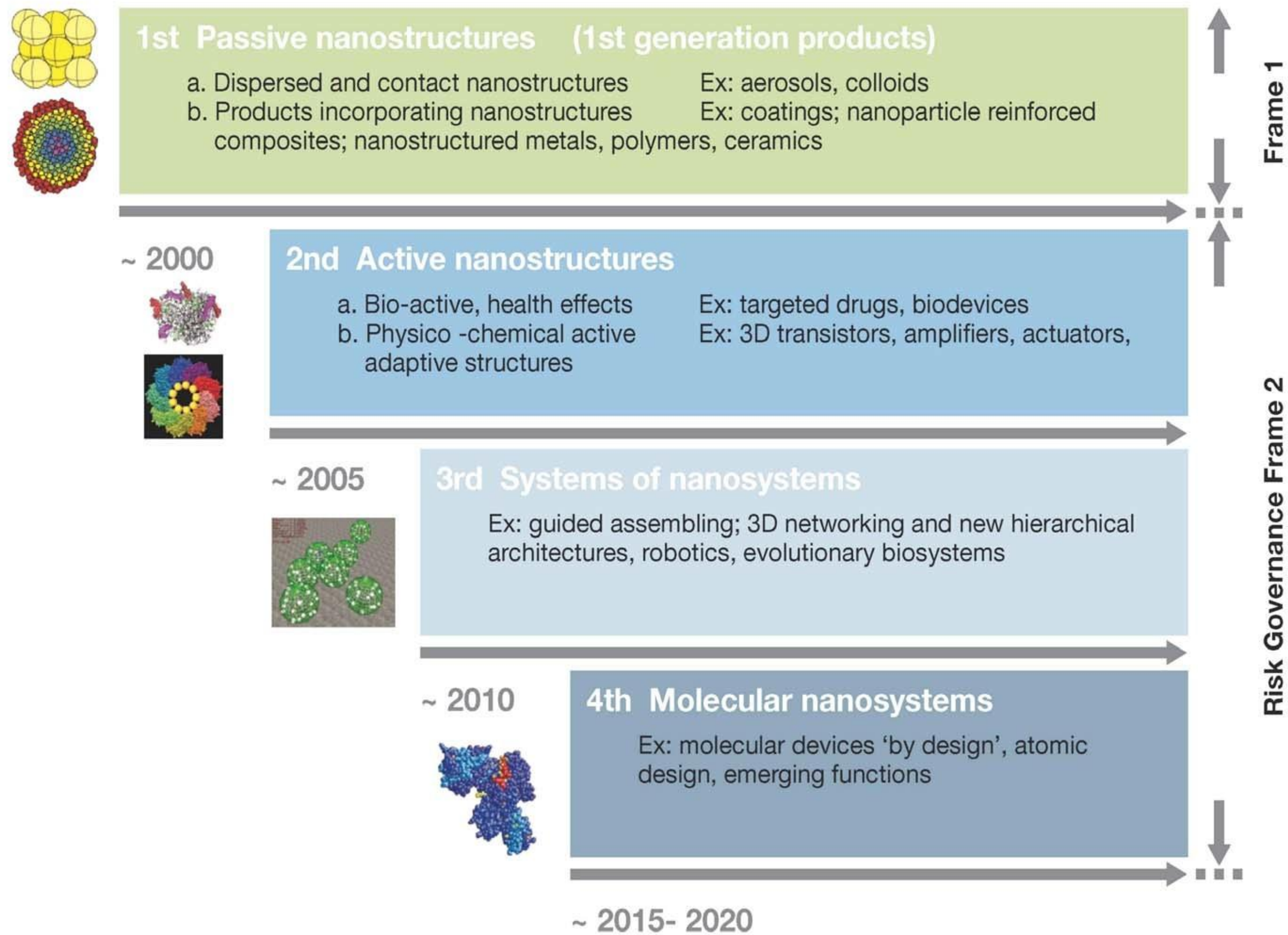

Three basic positions in the NT debate

- Restrictive: Regulation is necessary to ensure that (potential) risks not overshadow (potential) benefits, that technologies are developed responsibly and that public interests are included in shaping the technology.

- Permissive: Regulation is not justified / cannot be implemented because of gaps in knowledge about impacts and limits to anticipatory knowledge. Regulation will jeopardize innovation, hinder technological progress and „is bad for business".

- Adaptive: New regulatory frameworks need to be designed that allow for the flexible implementation of measures as the technology itself advances and knowledge about impact increases.

Multi Stakeholder Dialogues

- Exchange between the relevant stakeholders about goals, interests, perspectives, knowledge and specific technology
- Aims: start dialogue, interactive exploration of goals, identification of (potential) consensus / dissent, development and evaluation of scenarios or strategies
- Purpose: discover commonalities and differences in perspectives of stakeholder groups, clarification of interests, feedback into organisations, development of policy options, create anticipatory knowledge

Welcome!

The NANoREG community:

- ❑ Partners
- ❑ New Partners
- ❑ National Coördinators and advisors
- ❑ Members of the Scientific Advisory Board
- ❑ Members of the NICC
- ❑ Representatives of the EC
- ❑ Representatives of International Organisations

State of the art: 1st 18 Month

- ❑ 18-Month Progress report: On track with some delay
- ❑ Review/advice Scientific Advisory Board
- ❑ Mid-term review meeting EC and NCs

State of the Art NANoREG project

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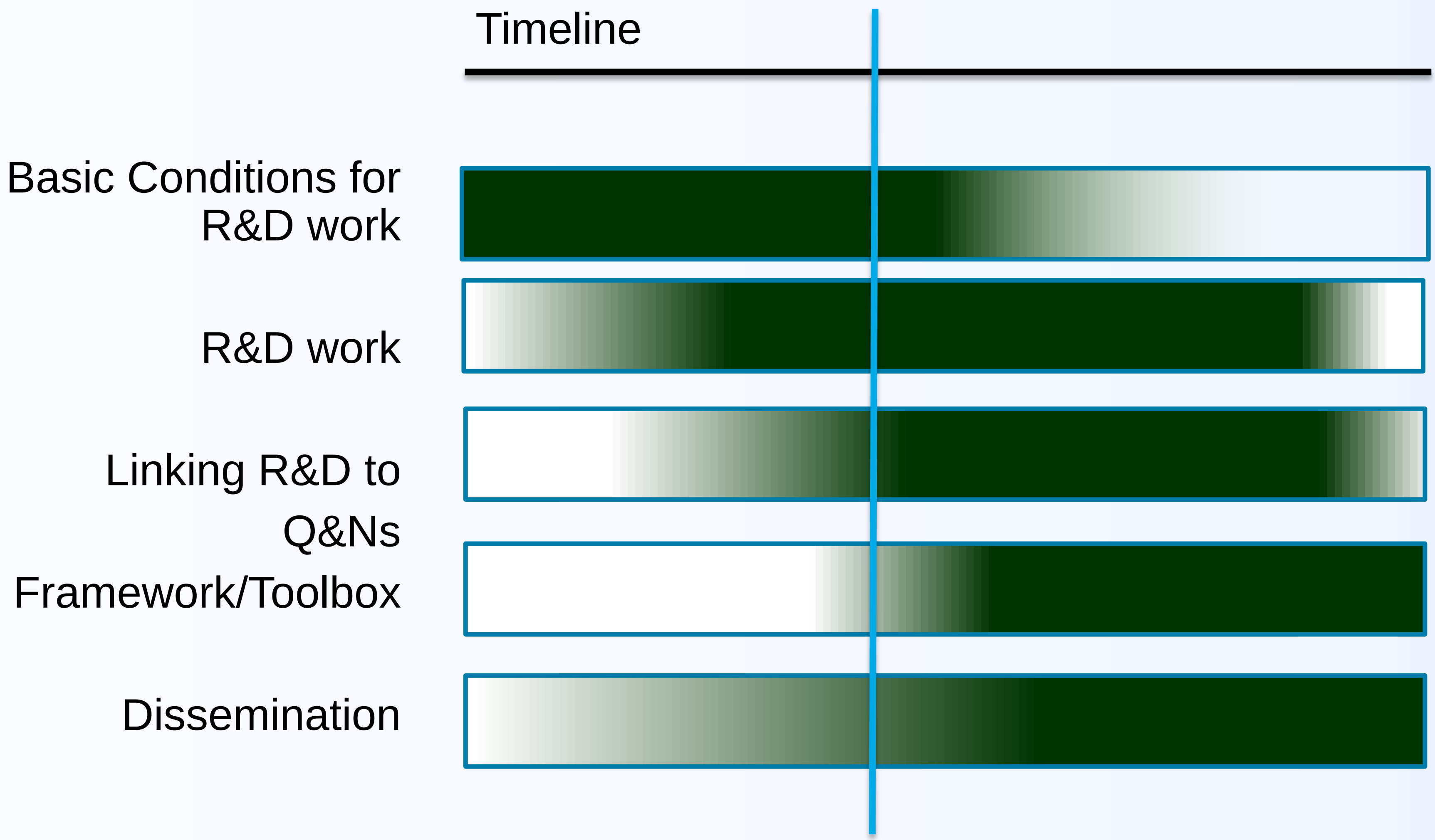

Challenges coming period

- Keeping focus in the R&D work on the regulatory Questions & Needs; (task 1.3)
- R&D work "of high quality" including data logging (summary feedback SAB)
- Development Regulatory Framework in collaboration with relevant international and global bodies;
- Shaping and filling the toolbox to make the Framework operational
- Expanding global collaboration aimed at Harmoni-zation and standardization of data management, test methods, methods for risk assessment etc (part of CSA PROSAFE)