Nanotechnologies

- Political and Societal Aspects of their Regulation -

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Nanotechnologies: The Present State of Regulation
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Outline

Oversight and regulation of nanotechnology

- What?
- Why?
- How?
- Further questions

The (anticipated) NT market

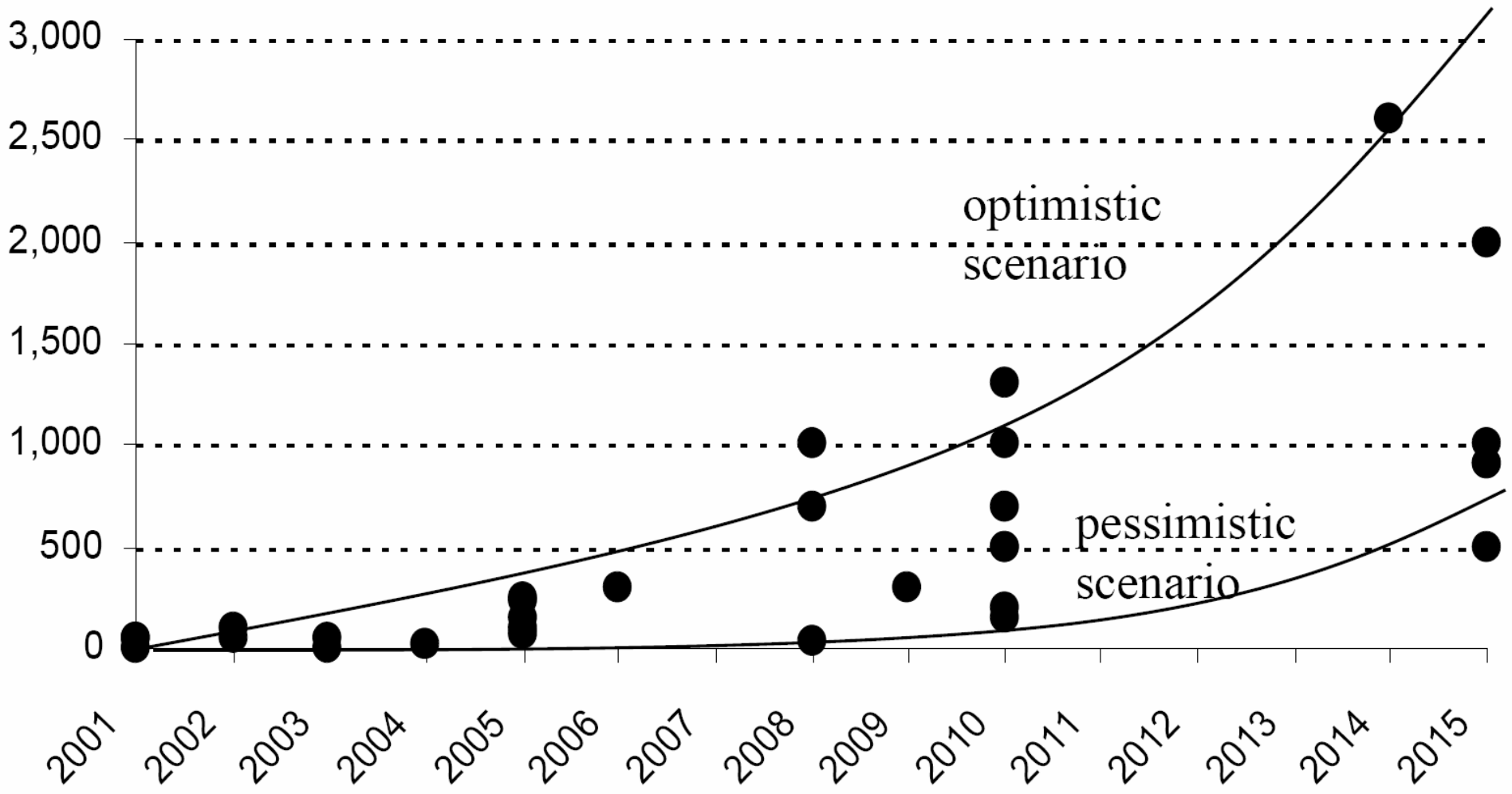
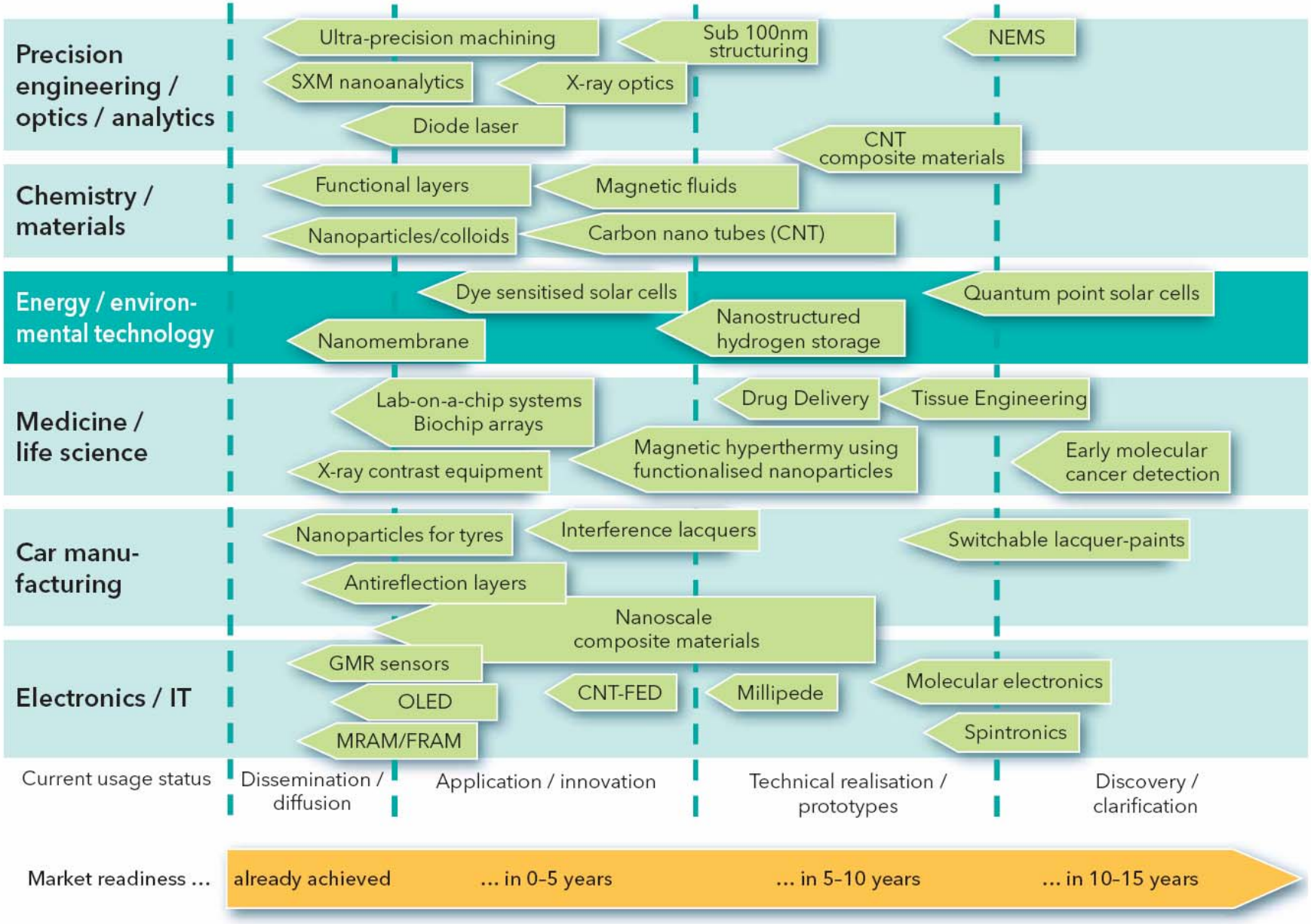


Figure 1: World market forecasts for nanotechnology in billion US Dollar. Diverse sources

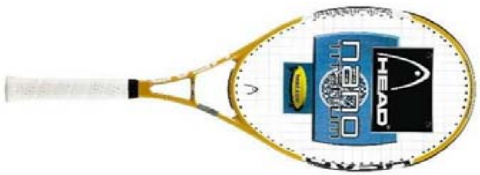
Source: A.Hullmann. The economic development of nanotechnology. EC DG Research, Brussels 2006

Nanotechnology – Products

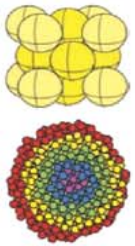


Source: adapted from Bachmann/Rieke 2004

Nanotechnology – Consumer Products



Four Generations of Nanotechnology

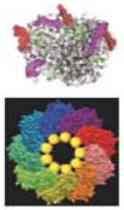


1st Passive nanostructures (1st generation products)

a. Dispersed and contact nanostructures — Ex: aerosols, colloids
b. Products incorporating nanostructures — Ex: coatings; nanoparticle reinforced composites; nanostructured metals, polymers, ceramics

Frame 1

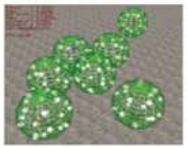
~ 2000



2nd Active nanostructures

a. Bio-active, health effects — Ex: targeted drugs, biodevices
b. Physico -chemical active adaptive structures — Ex: 3D transistors, amplifiers, actuators,

~ 2005



3rd Systems of nanosystems

Ex: guided assembling; 3D networking and new hierarchical architectures, robotics, evolutionary biosystems

~ 2010

4th Molecular nanosystems

Ex: molecular devices 'by design', atomic design, emerging functions

~ 2015- 2020

Risk Governance Frame 2

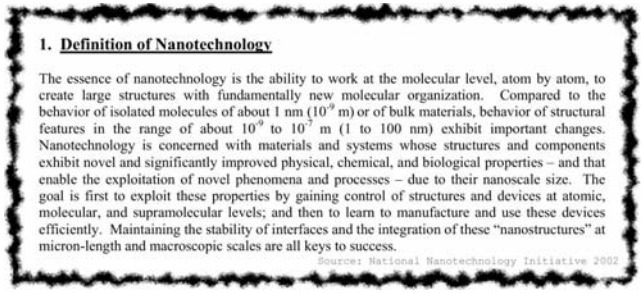
Source: IRGC 2006

Nanotechnology – Definitions

Nanotechnology is the manipulation or self-assembly of individual atoms, molecules, or molecular clusters into structures to create materials and devices with new or vastly different properties. (EP 2006)

Nanotechnology is the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling and manipulating matter at this length scale. (NNI 2007)

The term 'nanotechnology' will be used here as a collective term, encompassing the various branches of nanosciences and nanotechnologies. Conceptually, nanotechnology refers to science and technology at the nano-scale of atoms and molecules, and to the scientific principles and new properties that can be understood and mastered when operating in this domain. (CEC 2004)



1. **Definition of Nanotechnology**

The essence of nanotechnology is the ability to work at the molecular level, atom by atom, to create large structures with fundamentally new molecular organization. Compared to the behavior of isolated molecules of about 1 nm (10^{-9} m) or of bulk materials, behavior of structural features in the range of about 10^{-9} to 10^{-7} m (1 to 100 nm) exhibit important changes. Nanotechnology is concerned with materials and systems whose structures and components exhibit novel and significantly improved physical, chemical, and biological properties – and that enable the exploitation of novel phenomena and processes – due to their nanoscale size. The goal is first to exploit these properties by gaining control of structures and devices at atomic, molecular, and supramolecular levels; and then to learn to manufacture and use these devices efficiently. Maintaining the stability of interfaces and the integration of these "nanostructures" at micron-length and macroscopic scales are all keys to success.

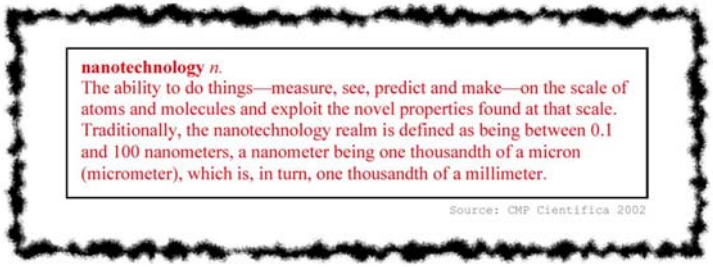
Source: National Nanotechnology Initiative 2002

What is nanotechnology?

In its formal sense, the 'nano' world is where science and technology reach dimensions and tolerances in the range 100 nanometres (0.1 micrometres) to 0.1 nanometres. (...)

So nanotechnology and nanoscience are concerned with materials science and its application at, or around, the nanometre scale. A more useful definition of nanotechnology is the application of science to developing new materials and processes by manipulating molecules and atoms. It is a collective term for a set of technologies, techniques and processes rather than a specific area of science or engineering.

Source: U.K. DTI (2003)



nanotechnology *n.*
The ability to do things—measure, see, predict and make—on the scale of atoms and molecules and exploit the novel properties found at that scale. Traditionally, the nanotechnology realm is defined as being between 0.1 and 100 nanometers, a nanometer being one thousandth of a micron (micrometer), which is, in turn, one thousandth of a millimeter.

Source: CMP Cientifica 2002

Nanotechnology – Definitions?

German Federal Ministry of Education and Research in an information document for the German Parliament (2007):

> Eine allgemein anerkannte Definition der Nanotechnologie existiert bis heute nicht. Weithin unbestritten ist aber, dass sie sich mit Strukturen befasst, die in mindestens einer Dimension kleiner als 100 nm sind.

("A generally accepted definition of nanotechnology does not exist until today. It is widely undisputed, however, that she is dealing with structures which are smaller than 100 nm in at least one dimension.")

Source: Bericht der Bundesregierung zum Veränderungsbedarf des bestehenden Rechtsrahmens für Anwendungen der Nanotechnologie. Bundestags-Drucksache 16/6337, 30.08.2007

What is Nanotechnology?

- No generally accepted definition
- Promise: technical exploitation of effects that occur in a dimension (1-100 nm) that was almost inaccessible so far
- Not a technology in a stricter sense: State of development and potential applications very heterogeneous
- Major part of current ‚nanotechnology' is basic science and fundamental research (N&N, 'NanoTechnoSciences')
- More hopes and promises than marketable technologies
- Interdisciplinary approach, no disciplinary identity
- 'enabling technology', 'umbrella term', 'empty signifier'
- 'Avantgarde label' - important part of societal debates about the future of technology and society

Terminology

- How terms like nanotechnology, nanomaterials, nanoparticles … are defined has consequences for the management, marketing, and oversight of the respective products and technologies.
- Clarification of terminology is essential to advancing efforts of governance: development of voluntary guidelines or standards, legislative action, risk assessment, ...
- Also of relevance for the public perception of NT (and the attitude towards it):

  "Nano is what people think that it is."

Four Regulatory Discourses

Currently, four interwoven discourses (about different subjects):

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

In a nutshell: Why regulate technologies?

- Production and use of technology have various impacts: on individuals, society, environment
- (Expected) impacts may be in accordance or in conflict with individual and collective goals, preferences, norms, values: health, safety, environment, lifestyle, distributive justice, …
- Regulation of technology shapes it and its impact – may constrain and condition its use (and sometimes the user)
- Pluralistic societies integrate a great variety of cultural habits, values, norms, beliefs, and worldviews
- Regulatory debates about technologies reflect these. They are debates about anticipations and expectations – and fights for predominance and political consensus.
- „Regulation is the technology of governance." (Wiener)

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

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.

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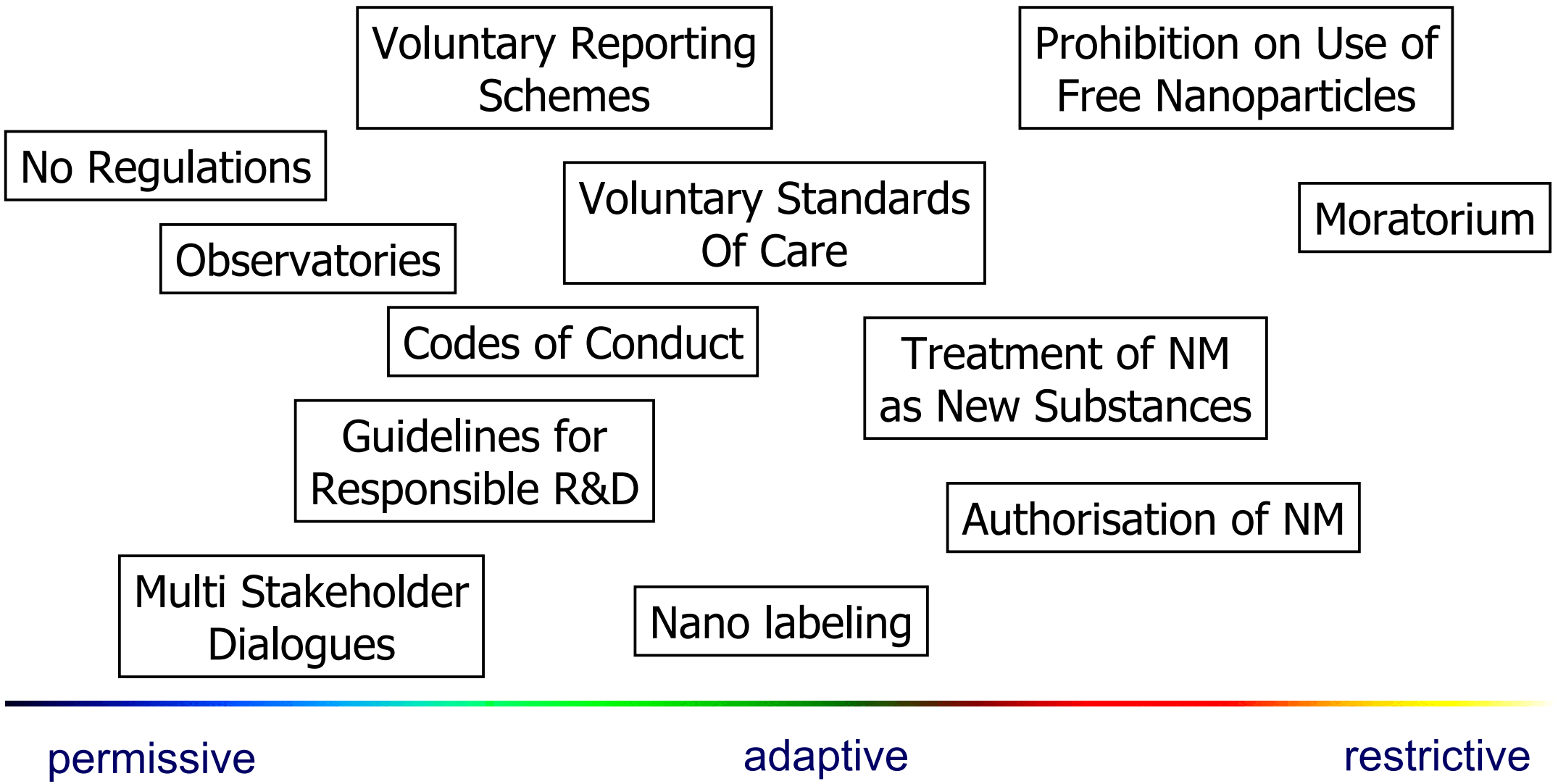
(Manufactured) Nanoparticles

- Manufactured nanoparticles already widely used in (consumer) products
- VCI 2006: 'Nanoparticles' are understood to mean solids produced as powder, or solids produced or dispersed in liquid media, whose individual particles have, in at least two dimensions, an extent of under 100 nm.
- Chemistry: elements, compounds (inorganic, organic), composites
- Morphology: Nanotubes, Nanowires, Nanocrystals, Quantum Dots, other
- Moving to nanoscale changes physical properties of particles: increase the ratio of surface area to volume, emergence of quantum effects, other morphology-dependent effects
- Interaction between nanoparticles may result in aggregates and/or agglomerates which may influence the properties
- Do different physical properties lead to different materials-biology interactions? Exposure? Risks for human health and/or the environment?

Spectrum of Regulation Proposals for MNP



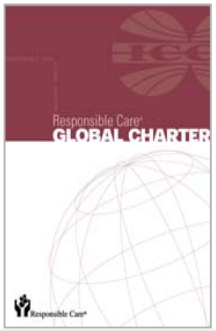
Nanotechnology Observatories

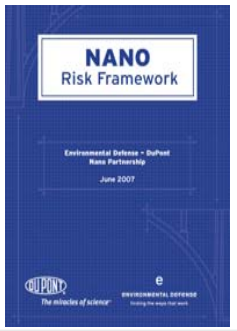
- Collate and analyze data regarding scientific and technological trends, economic developments and expectations, EHS impacts and societal issues
- Make the information accessible for decision-makers (and the general public)
- Provide systematic overview about state of research, development and application (+ communication, acceptance)
- Foci (NT, EHS, NP) and roles (information, assessment, participation) may differ
- „institutions of permanent attention“

- Examples: observatoryNANO (EU), OMNT (FR), Navigator Network (NZ), NanoTrust (AT), NanoCare Cluster (DE)

Codes of Conduct

- Set of principals, values, standards, or rules of behavior that guide the decisions, procedures and systems of an individual or organization
- Form of self-policing (self-regulation)
- Different types:
  - company or industry internal (e.g. BASF, Evonik, Swiss Retailers, Responsible Care Global Charter),
  - company or industry with external monitoring (and enforcement) (e.g. DuPont-ED)
  - embedded in multi-stakeholder system (e.g. EC, NIA, NanoDialog)





Codes of Conduct

Advantages:

- Flexible, build on industry's knowledge and capacity
- Generate knowledge that will be publicly available
- Can be implemented easily and quickly, cost-effective
- Non-legislative (self-)regulation: relieves the legislature

Disadvantages:

- Can be too flexible if not properly defined
- Public trust without monitoring? Monitoring can be difficult and costly. Enforcement mechanisms?
- Shift of responsibilities from legislature / authorities to industries. Credibility? Political transparency?

Participatory Approaches

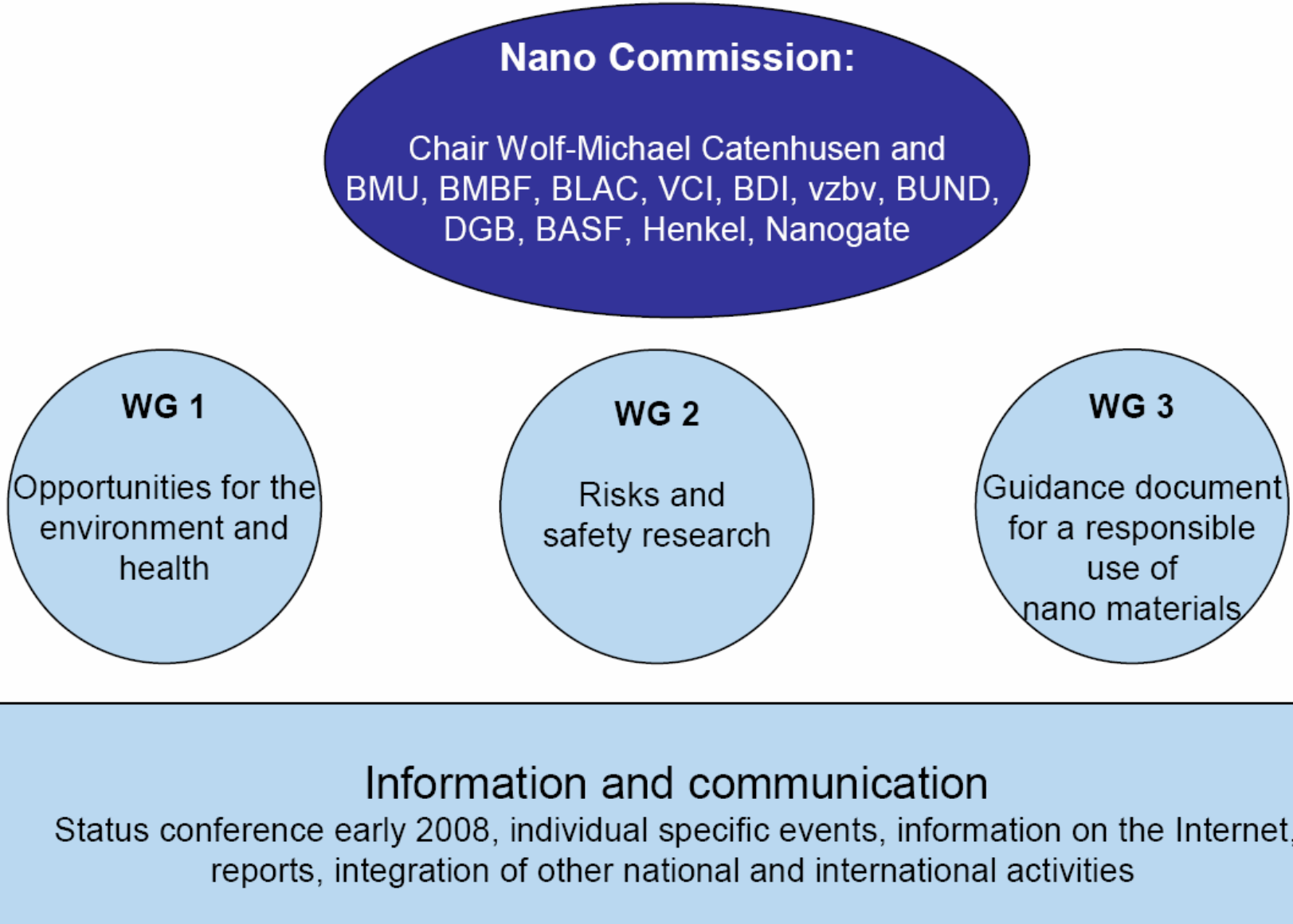
- Pragmatic argument: Broaden the knowledge base for decision-making in science and technology policy
- Normative argument: Render the decision-making process more democratic
- Involving groups or individuals in the preparation and negotiation of STP decisions that „usually" do not participate
- Participants: Experts, public officials, industry executives, stakeholders of a project or policy, average citizens, …
- Various forms: depending on objectives, topics, issue-framing, participants, but also time, budget
- May support forms of „anticipatory governance"
- Examples: Consultations, delphi studies, dialogues, expert panels, consensus conferences, scenario workshops, …

Multi Stakeholder Dialogues

- Exchange between the relevant stakeholders about goals, interests, perspectives, knowledge re a 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, overcome blockades, feedback into organisations, development of policy options, create anticipatory knowledge

- Examples: Nano Safety for Success (CEC), NanoDialog (D)

Structure of NanoDialog



Source: BMU

Participatory Projects involving the GP

- Methods (occasionally modified):
  - Citizens Jury
  - Consensus Conference
  - Focus Groups
- Examples of projects including participatory elements:
  - Rathenau (NL): Kleine Technologie - Grote Gevolgen (2004) / Nano in Focus (2006)
  - Teknologirådet (DK): Borgeres holdninger til nanoteknologi (2004)
  - USC (US): South Carolina Citizens' School of Nanotechnology (2004)
  - CSIRO (AU): Bendigo Workshop (2004) / Citizens' Panel on NT (2005)
  - NanoJury UK (2005)
  - UWisc (US): Madison Area Citizen Consensus Conference (2005)
  - DEMOS (UK): The NanoDialogues (2006)
  - EU: Projects Nanologue und NanoDialogue (2005/06)
  - TA-SWISS (CH): publifocus Nanotechnologie (2006)
  - BfR (D): Verbraucherkonferenz Nanotechnologie (2006)
  - Conseil Régional d'Ile-de-France (F): Conférence de Citoyens sur Les Nanotechnologies (2007)
  - ITAS (D): Laien-Fokusgruppen zu synthetischen Nanopartikeln (2007/08)
  - MPS (D): Jugendforum Nanomedizin (2008)

Participatory Projects: Recurring Themes

- Definition / terminology
- Worries about impacts on health and environment (nanoparticles)
- Systematic investigation of risks, government *as well as* manufacturers and suppliers should be responsible
- Regulatory aspects: Vigilant and active government, but no moratorium for research
- Declaration / Labelling
- Information / openness / involvement
- Criticism of intransparency of research, especially in the private sector
- Pro: nano for medicine, environment, energy
- Very sensible: nano in food
- Con: Military applications
- Social segregation, ‚nano divide' (nationally and globally)

Labeling

Yes:

- Will help people to appreciate nanotechnology
- May divide the „real" nano from the marketing use
- Enables customers to make informed choice
- Respects „right to know" - builds responsibility and trust

No:

- Problem of lacking definitions and nomenclature – what to label and how
- May be misleading without contextual information
- May backfire if something happens elsewhere in the NT realms
- Fear for consumer backlash

Uncertainty in Decision-making

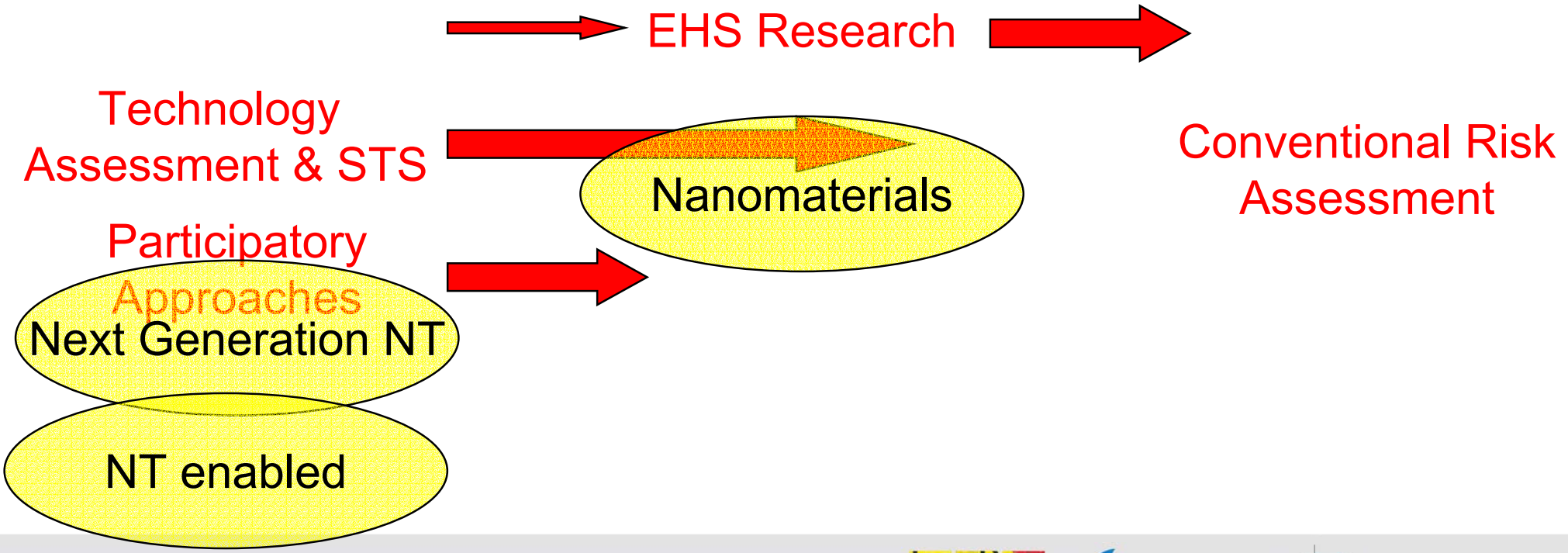
Unknown unknowns	Known unknowns	Knowns
Great Uncertainty most features of the situation neither known nor well-defined (options, their possible consequences, reliability of information, value of different outcomes)	**Uncertainty** no sufficient basis for assigning a precise and accurate likelihood to a particular outcome, most other features of the situation well-defined and known	**Risk** both the likelihood of a particular outcome, and the nature of its impact, are well understood
Precaution anticipate, identify and reduce the impact of 'surprises'	**Precautionary Prevention** reduce potential hazards	**Prevention** reduce known risks

Uncertainty in Decision-making

Great Uncertainty	Uncertainty	Risk
Precaution	Precautionary Prevention	Prevention

Hard law: Limits, Authorizations, Bans, …

Soft law: Guidelines, Principles, CoC, CoP, …



Regulatory Challenges (1)

- Lack of basics: definition, nomenclature, methods, data
- Terminology matters! To governance, regulation, communication
- Focus: Heterogeneity of NT and its impacts calls for different approaches to different technologies and applications
- Recently statutes regulate substances and products rather than technologies – fit into regulatory system?
- Regulation in many countries dispersed through multiple agencies with different responsibilities and capabilities – coordination and capacity-building
- Promotion and oversight/regulation of emerging technologies within the same institution?

Regulatory Challenges (2)

- Understand the interaction (synergies and conflicts) between and the impacts of different regulatory measures
- Consider benefits and risks of regulatory measures simultaneously
- Include knowledge gaps in regulatory framework
- Allow for dynamism: regulation should be able to react to changes in knowledge or threats in due time
- Observe the achievements of self-regulation and „soft law" – Prepare (and announce) a back-up regulatory strategy?
- Precautionary approaches? … without blocking innovation

Thank You

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