



# Nanotechnology: Risk Governance

Second Annual Nanotechnology Dialogue  
Brussels, October 2, 2008  
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University of Stuttgart and Dialogik Institute

# Soil Association first organisation in the world to ban nanoparticles - potentially toxic beauty products that get right under your skin



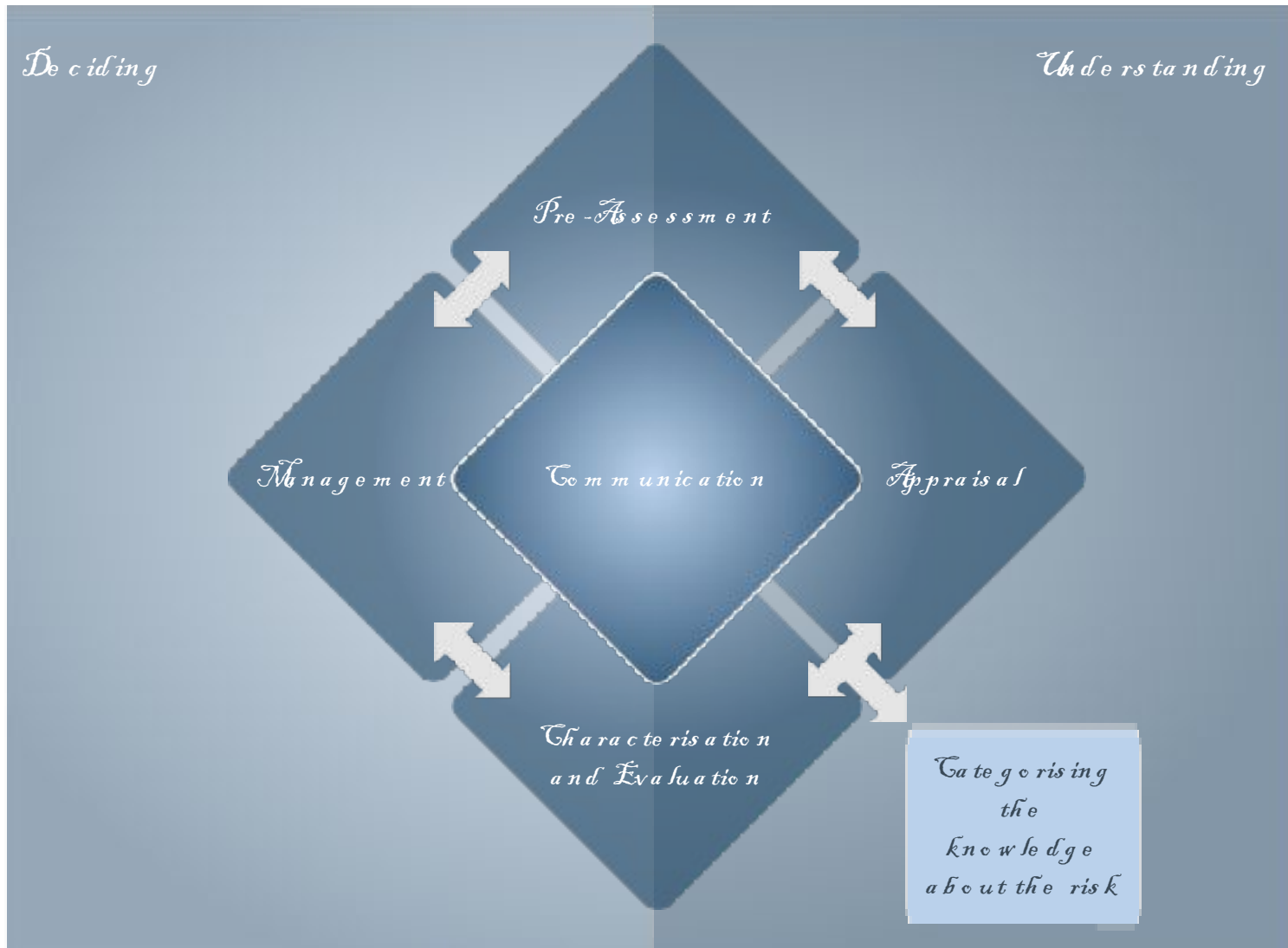
Tuesday 15 January 2008

“As of January 2008, the Soil Association has banned the use of man-made nanomaterials from all Soil Association certified organic products. This applies particularly to health and beauty products, but also to food and textiles...we are the first organisation in the world to take regulatory action against the use of nanoparticles to safeguard the public. This initiative goes to the core of the organic movement's values of protecting human health...Initial studies show some negative effects and there is a list of potential health impacts that have yet to be investigated by scientists.”

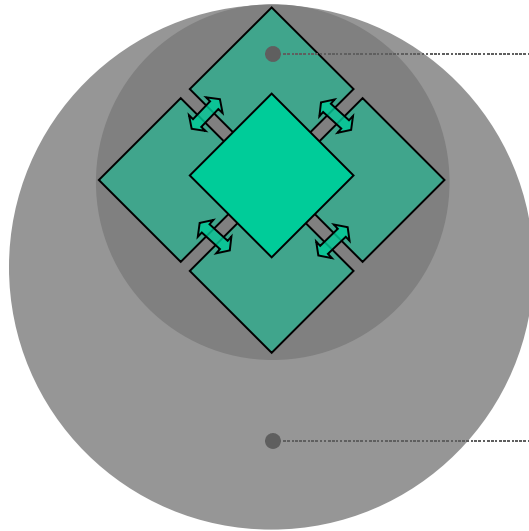
Soil Association (UK) press release of 15 January 2008

# Requirements for Risk Governance Models

- Concepts that link risk assessment with risk perception and socio-cultural processing of risk
  - Avoiding relativist view of knowledge but including social constructions of risks
  - Link between risk assessment, management and communication
- Concepts that link physical risk analysis with financial, economic and social risk;
  - Explore social amplification pathways
  - Consider trans-sectoral and trans-boundary ramifications
- Concepts that link risk theory with organizational capacity building and management competency
  - Systematic use of management sciences and decision aiding
  - Emphasis on risk communication between and among agencies and professionals



# RISK GOVERNANCE INCLUDES AND IS SENSITIVE TO CONTEXT



## Core Risk Governance Process

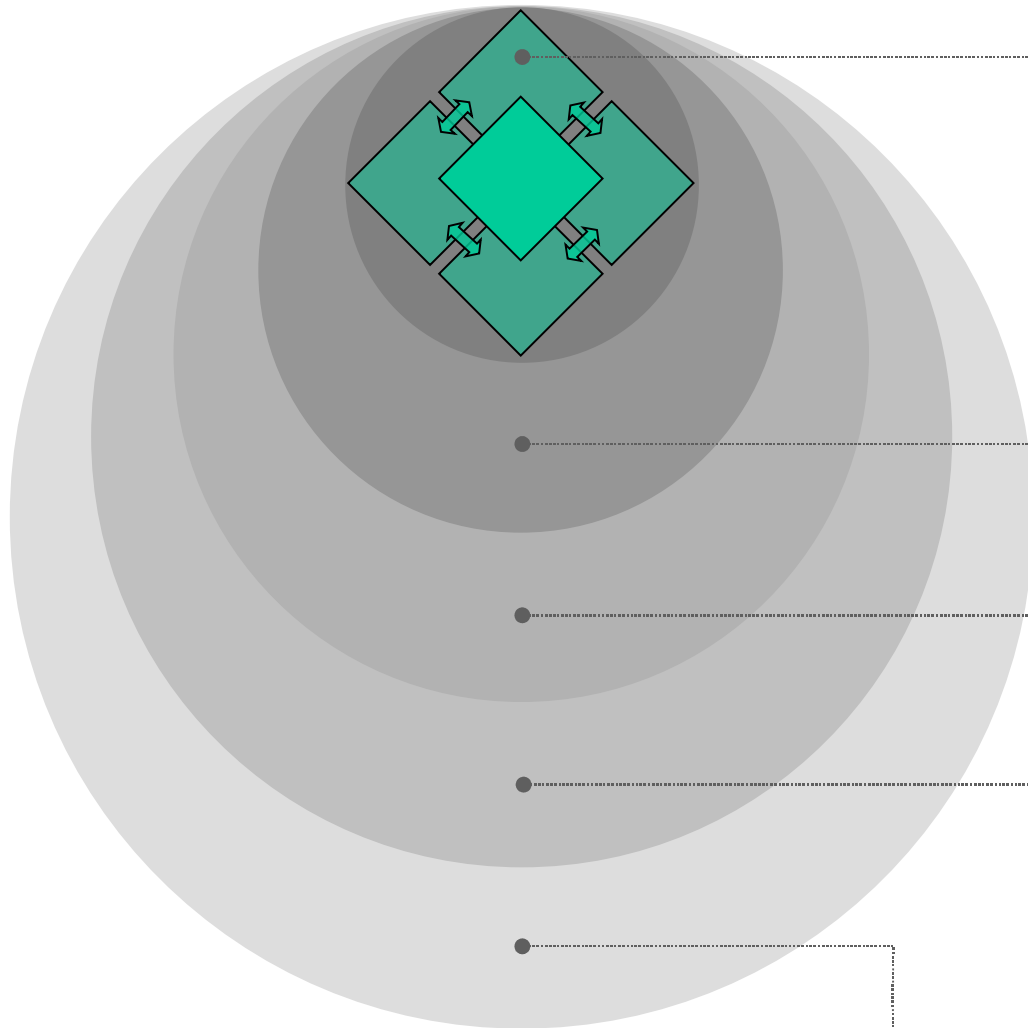
- pre-assessment
  - risk appraisal
    - risk assessment
    - concern assessment
- evaluation: tolerability / acceptability judgement
  - risk management
  - communication

## Organisational Capacity

- assets
- skills
- capabilities

Most risk management processes are done in this context only

# RISK GOVERNANCE GOES MUCH FURTHER



## Core Risk Governance Process

- pre-assessment
  - risk appraisal
  - risk assessment
  - concern assessment
- evaluation: tolerability / acceptability judgement
  - risk management
  - communication

## Organisational Capacity

- assets
- skills
- capabilities

## Actor Network

- politicians
- regulators
- industry/business
  - NGOs
  - media
- public at large

## Social Climate

- trust in regulatory institutions
- perceived authority of science
- degree of civil society involvement

## Political & Regulatory Culture

→ different regulatory styles

## *Phase 1*

# **PREASSESSMENT**

# Importance of Framing

Looks like a high risk from the outside





# Importance of Framing

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But consider this...



# Importance of Framing

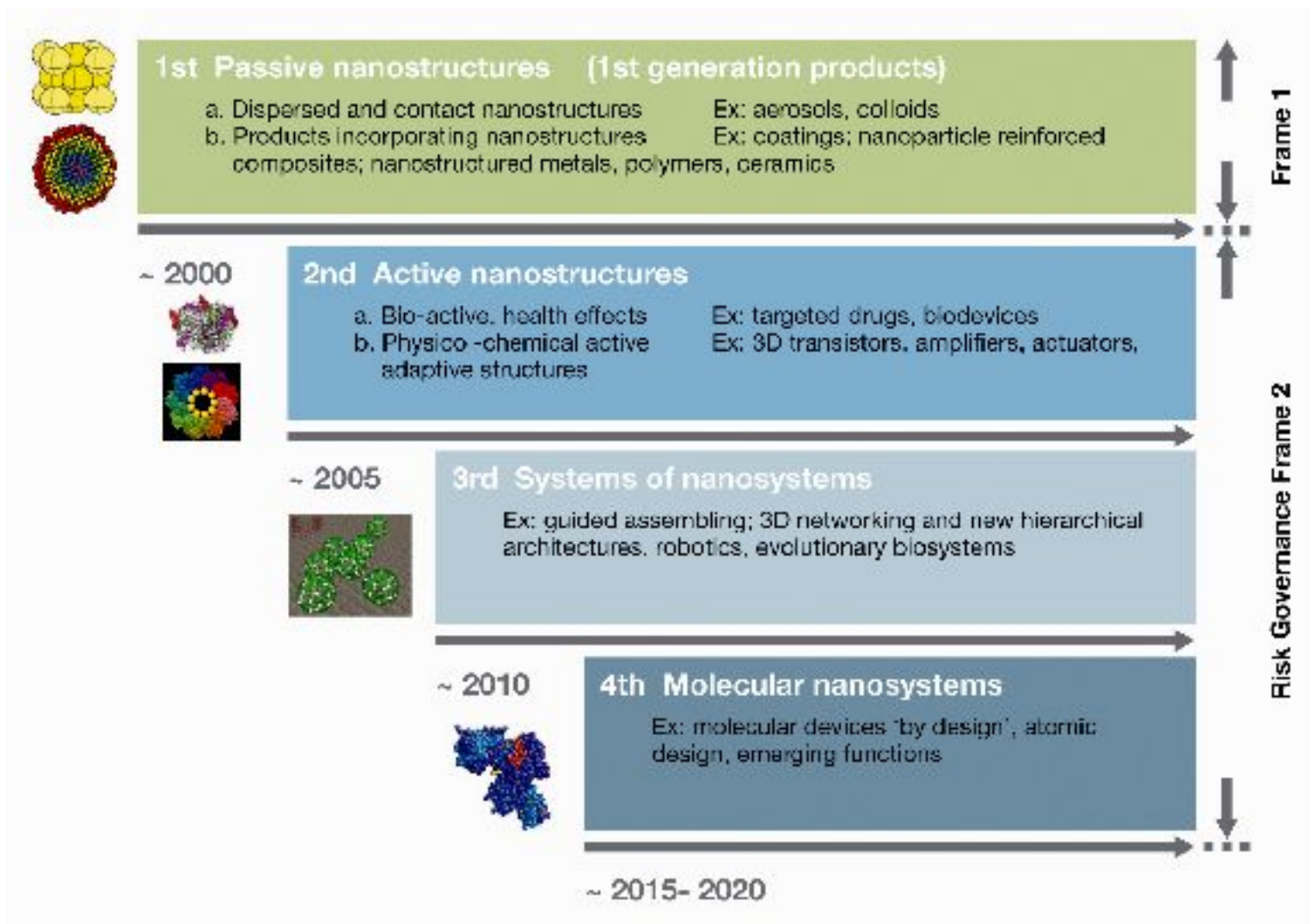
Or this...



# IMPORTANCE OF FRAMING

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- *Frames represent social, economic and cultural perspectives*
  - Challenge or problem
  - Opportunity or risk
  - Innovation or intervention
  
- *Frames determine boundaries of what is included and excluded*
  - Time and duration (future generations, sustainability)
  - Location and space (the universe, all nation, Belgium, Brussels)
  - Social class and stratus (vulnerable groups, poor, immigrants)
  - Types of adverse effects (physical, mental, social, cultural)
  - Primary or secondary impacts (ripple effects)
  - Criteria taken into account (risk reduction, cost, benefit, equity, environmental justice, value violations...)



# TWO MAJOR FRAMES FOR NANOTECHNOLOGY RISKS

- **Frame 1.** The context of classic technology assessment looking into the impacts derived from the application of nanoparticles and other passive nanostructured materials in different areas of application (such as paint, cosmetics, food, and coatings). This frame is most suitable for issues related to the first generation of nanoproducts (passive nanostructures)
- **Frame 2.** The context of social desirability of innovations looking into processes of modernization, changes in the interface between humans and machines/products and ethical issues of the boundaries of intervention into the environment and the human body. This frame addresses issues related to the future generations of nanoproducts (active nanostructures and nanosystems, and long-term implications of nanotechnology)

# NANOTECHNOLOGY RISK FRAMES



Nano-technology Risk Debate	Hazard	Exposure	Risk
<b>Frame 1</b>	Testing strategies for assessing toxicity; Improved protocols for assessing particle toxicity (for example surface-based testing)	Exposure monitoring methodologies. New protocols for measuring exposure (exploring complexity)	Risk assessment methodologies; Communication and education concerning EHS and ELSI.
<b>Frame 2</b>	Identifying the hazards using scenarios; Matrix for assessing the identified hazards	Estimation of exposure for events with great uncertainties and ambiguities, including black swans	Impact assessment, including concerns Communication and education Developing capacity to address uncertain/ unknown developments.

## *Phase 2*

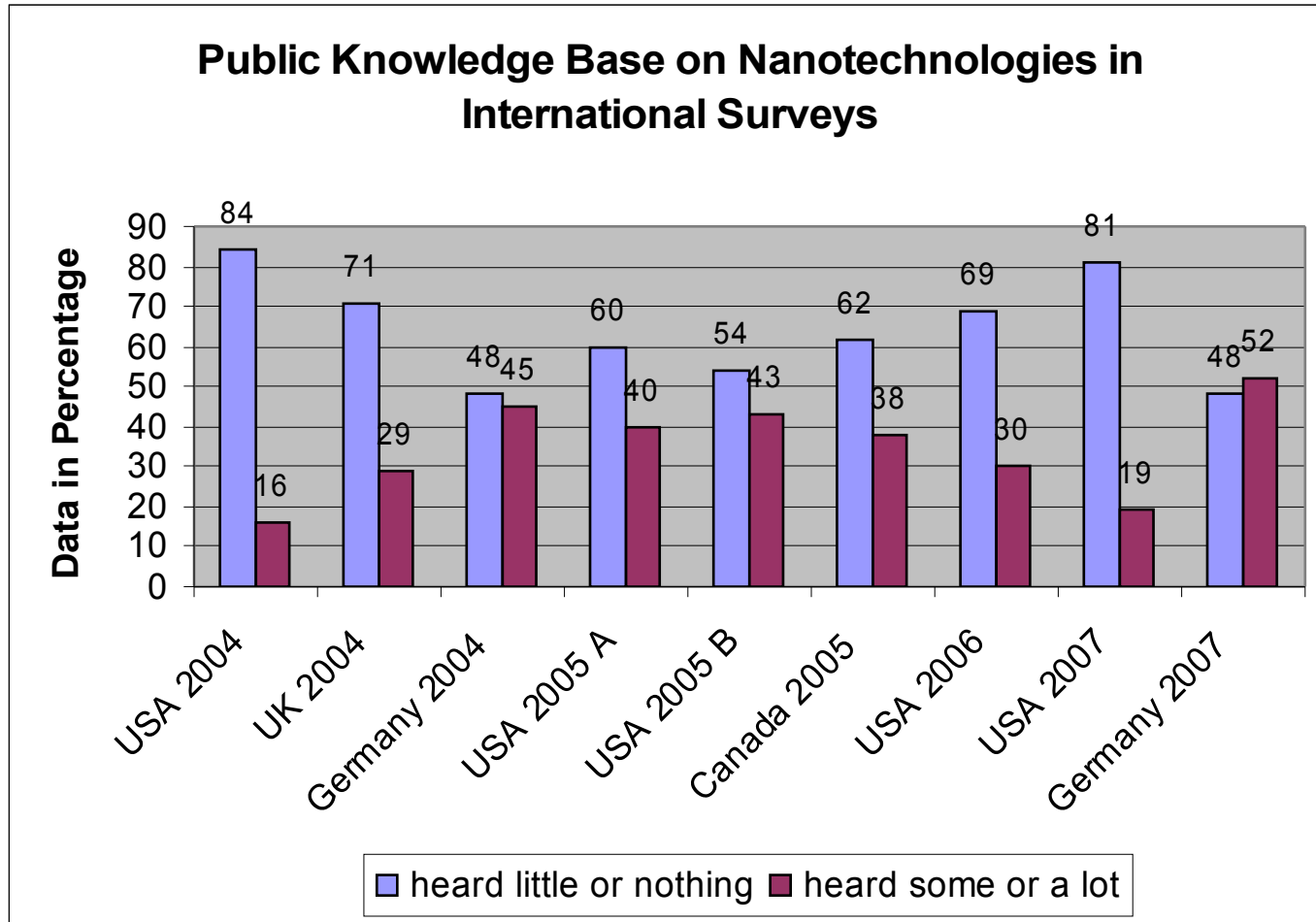
# **APPRAISAL**

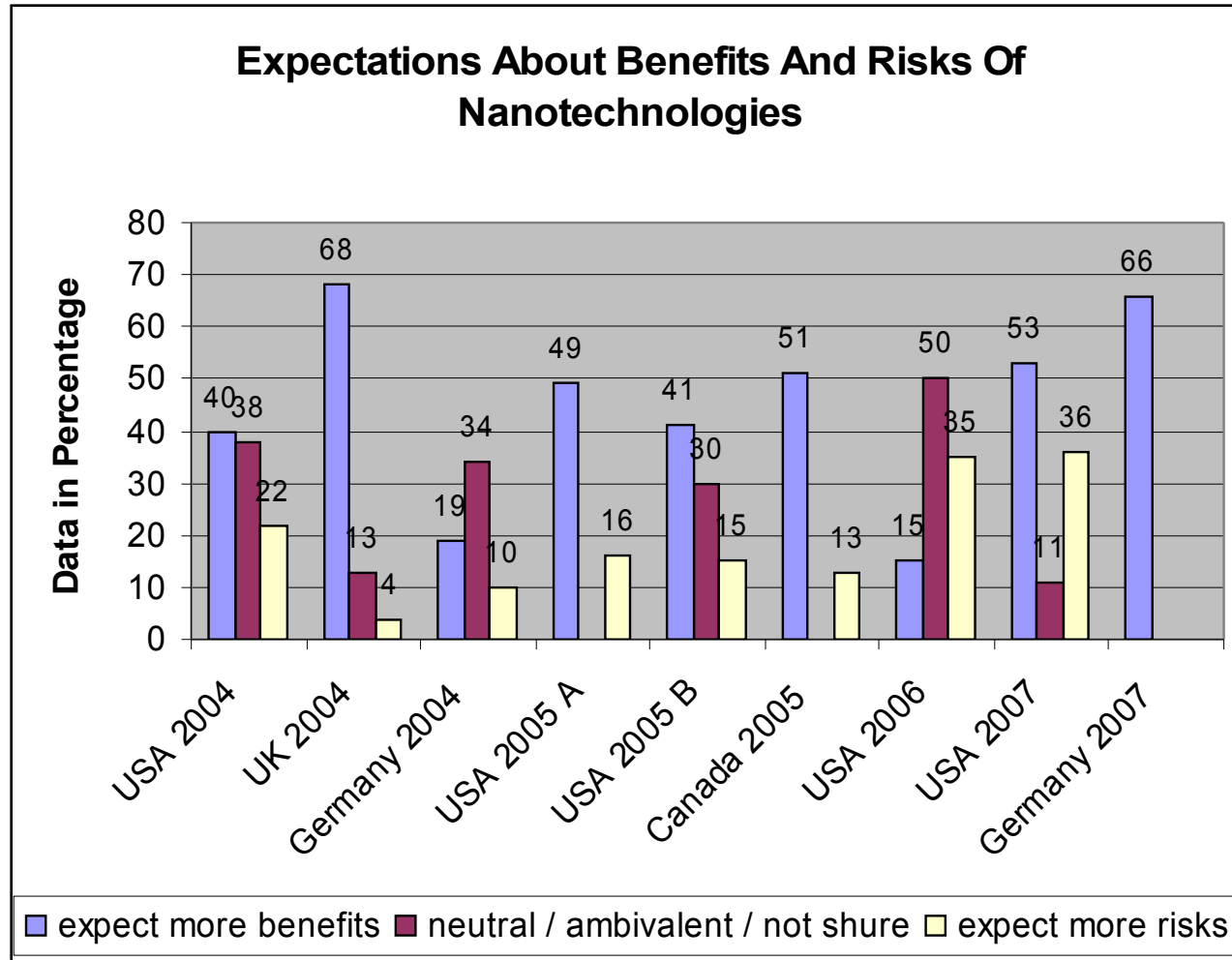
- **Risk Assessment**
  - Hazard identification and estimation
  - Exposure assessment
  - Risk estimation
  
- **Concern Assessment**
  - Socio-economic impacts
  - Economic benefits
  - Public concerns (stakeholders and individuals)



*How do values and emotions impact on how the risk is perceived?*

- ▶ What are the public's **concerns and perceptions**?
- ▶ What is the **social response** to the risk? Is there the possibility of political mobilisation or potential conflict?
- ▶ What role are existing institutions, governance structures and the media **playing in defining public concerns**?
- ▶ Are risk managers likely to face important controversies (ambiguities) arising from **differences in stakeholder objectives and values, or from inequities in the distribution of benefits and risks**?



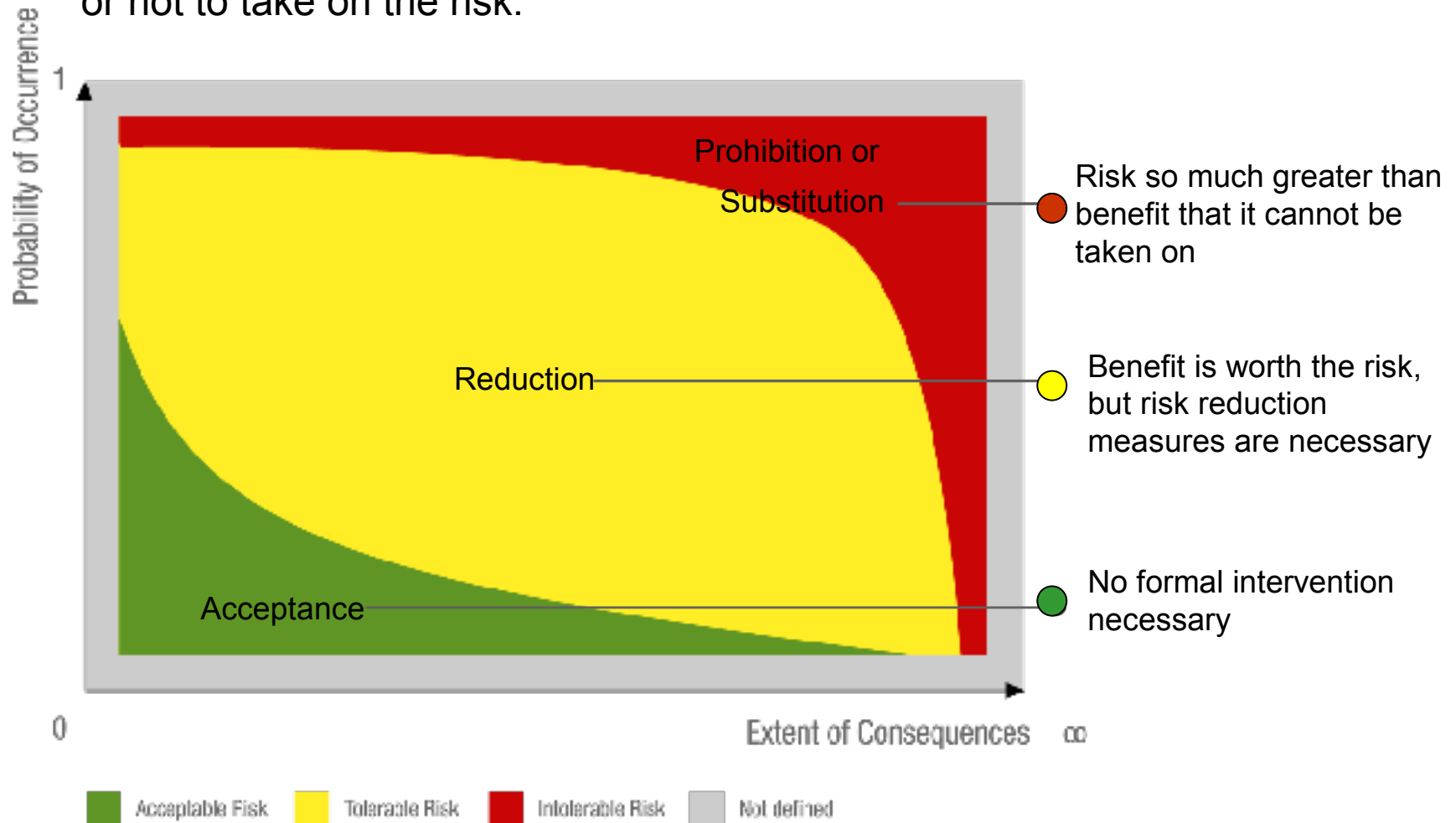


- Overall still low awareness but growing vigilance
- More attention when nanoparticles appear in food or cosmetics due to direct contact with the body (skin and intake);
- Mainly positive associations but growing concern about risks
- Nanoparticles are perceived by many as another technological controversy like GMOs (matches existing belief systems)
- Little information so far by industry on potential risks, particularly the food industry (perception of secrecy and lack of transparency);
- Lack of perceived competence and trust in public authorities;
- Lack of trust towards industry and public regulators

## *Phase 3*

# **Tolerability and Acceptability Judgment**

Based on **both the evidence from the risk appraisal and evaluation of broader value-based choices and the trade-offs involved**, decide whether or not to take on the risk.

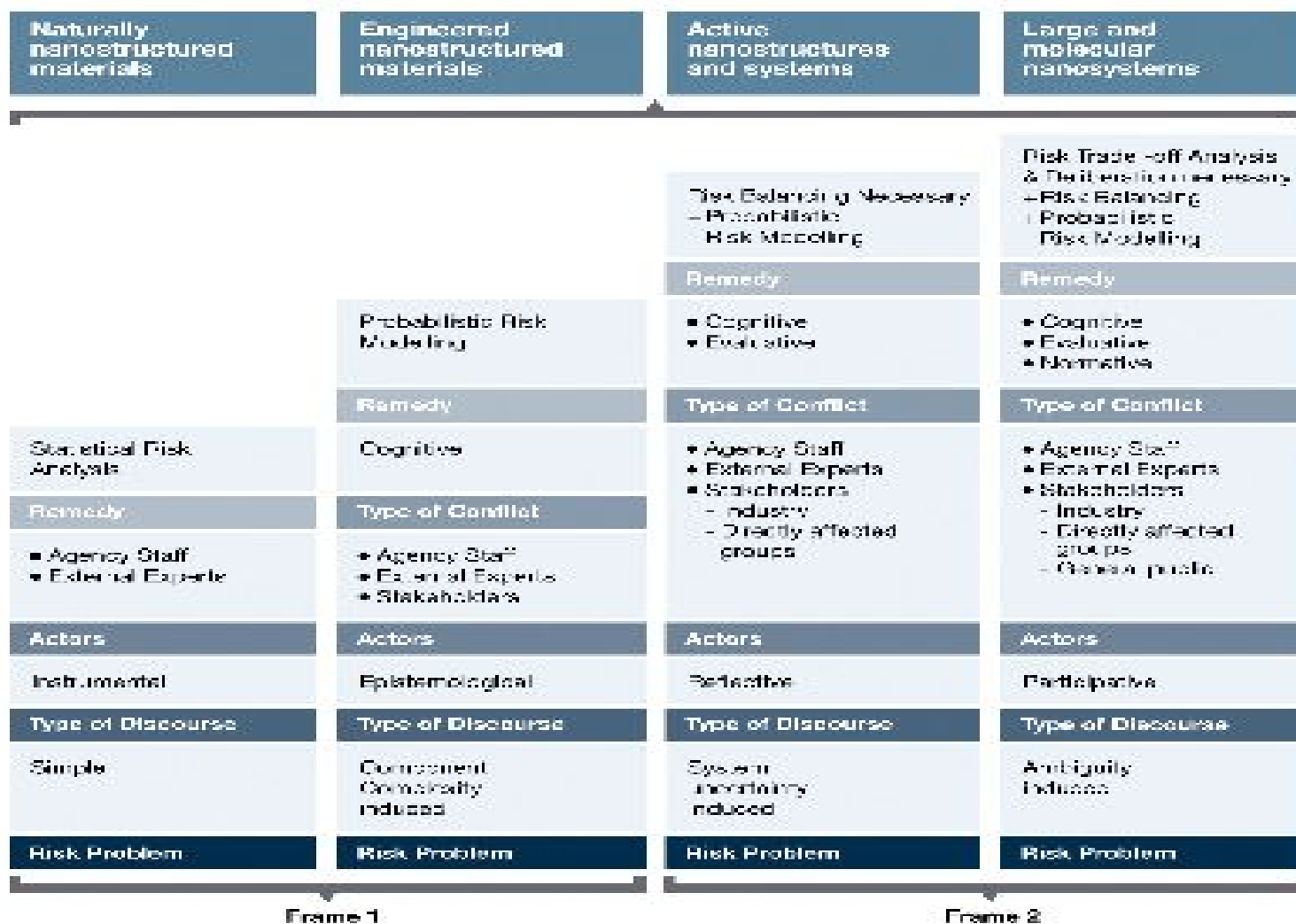


## *Phase 4*

# **RISK MANAGEMENT**

- **Simple** risk problems can be managed using a ‘**routine-based**’ **strategy**, such as introducing a law or regulation
- **Complex** risks may be best addressed by accessing and acting on the best available scientific expertise, aiming for a ‘risk-informed’ and ‘**robustness-focussed**’ **strategy**
- **Uncertain** risks are better managed using ‘precaution-based’ and ‘**resilience-focussed**’ **strategies**, to ensure the reversibility of critical decisions and to increase a system’s capacity to cope with surprises
- **Ambiguous** risk problems require a ‘**dialogue-based**’ **strategy** aiming to create tolerance and mutual understanding of conflicting views and values with a view to eventually reconciling them





<b>Function:</b> <b>Type of Discourse:</b> <b>Participants:</b>	Allocation of risks to one or several of the four routes Design discourse A team of risk and concern assessors, risk managers, stakeholders and representatives of related agencies
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## *Complementary Phase*

# **Risk Communication**

## ▶ Pre-assessment

- ▶ Informing other agencies and assessing who is affected and who is mandated to take responsibility
- ▶ Inviting views of affected stakeholders

## ▶ Appraisal

- ▶ Requesting and receiving appropriate scientific advice on the risk
- ▶ Requesting and receiving scientific advice on people's concerns

## ▶ Evaluation

- ▶ Communication of appraisal findings (if they are clear)
- ▶ Involving all affected agencies and stakeholders if risk appraisal findings are uncertain or ambiguous
- ▶ Deliberations concerning values / perspectives and to evaluate trade-offs

## ▶ Management

- ▶ Inclusion of appropriate stakeholders in the decision making process
- ▶ Communication of the decision / regulation / advice

# CONCLUSIONS

- ▶ Standardised nomenclature, measuring and handling systems
  - ▶ Need for an agreed, international approach to how to define, characterise, measure, test and validate products and processes
  
- ▶ Better understanding of risk
  - ▶ Increase proportion of public and private funding devoted to risk assessment
  
- ▶ Improved data sharing
  - ▶ In order to enable a common understanding of risks – and deal with them if they emerge – publish research findings (including research by industry)
  
- ▶ Understand the full implications
  - ▶ Undertake specific research into the wider, societal implications of active nanotechnology applications, to identify potential societal concerns and environmental impacts

- ▶ Distinguish between Frame 1 and Frame 2
  - ▶ Stress the differences between bonded, passive nanomaterials and active nanostructures and systems
  - ▶ Ensure societal concerns regarding Frame 2 applications do not confuse people's thinking about Frame 1 applications
  
- ▶ Improve communication strategies
  - ▶ More proactive engagement by the industry
  - ▶ Full transparency about ingredients of food and cosmetics
  - ▶ Public information campaigns by coalition of trustworthy institutions
  
- ▶ Engage the public and make participation effective
  - ▶ The public will not have a single unified view of nanotechnology
  - ▶ All views need to be recognised and addressed
  - ▶ Seek participation, not comment

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# QUOTE

- “What man desires is not knowledge but certainty.”  
*Bertrand Russell*
- Policy makers cannot produce certainty but can help people to develop coping mechanisms to deal prudently with the necessary uncertainty that is required for societies to progress





**This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.**