PROSO
ENGAGING SOCIETY FOR RRI

Empowering societal actors through responsible Research and Innovation

Societal Engagement for RRI

NanoCap – Capacity Building for Civil Society Organisations

NanoCap

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BUREAU KLB
ONDERZOEK
ADVIES
PROCES

The project is financed by the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement no 665947 and runs from January 2016 to February 2018.

Some considerations in 2005 to start NanoCap

- ✓ Cheering and alarming publications on potentials and risks of NT
- ✓ Limited scientific knowledge and uncertainties on properties, use, release, uptake
  - *hazards, solubility, absorption through lungs/blood-brain barrier/skin, reactivity, ROS-formation etc.*
  - *physical-chemical properties: size, shape, structure, surface*
- ✓ Existing regulations not fit for nano – no governance framework
- ✓ Strongly conflicting interests amongst stakeholders
  - *Industry, Governmental Authorities, Environmental NGOs, Trade Unions, Public, Scientists*
- ✓ Limited 'practical' knowledge amongst users and CSOs
- ✓ Generally limited resources for CSOs for structural capacity building
- ✓ Nano is a good testcase after finalizing chemical legislation (REACH)

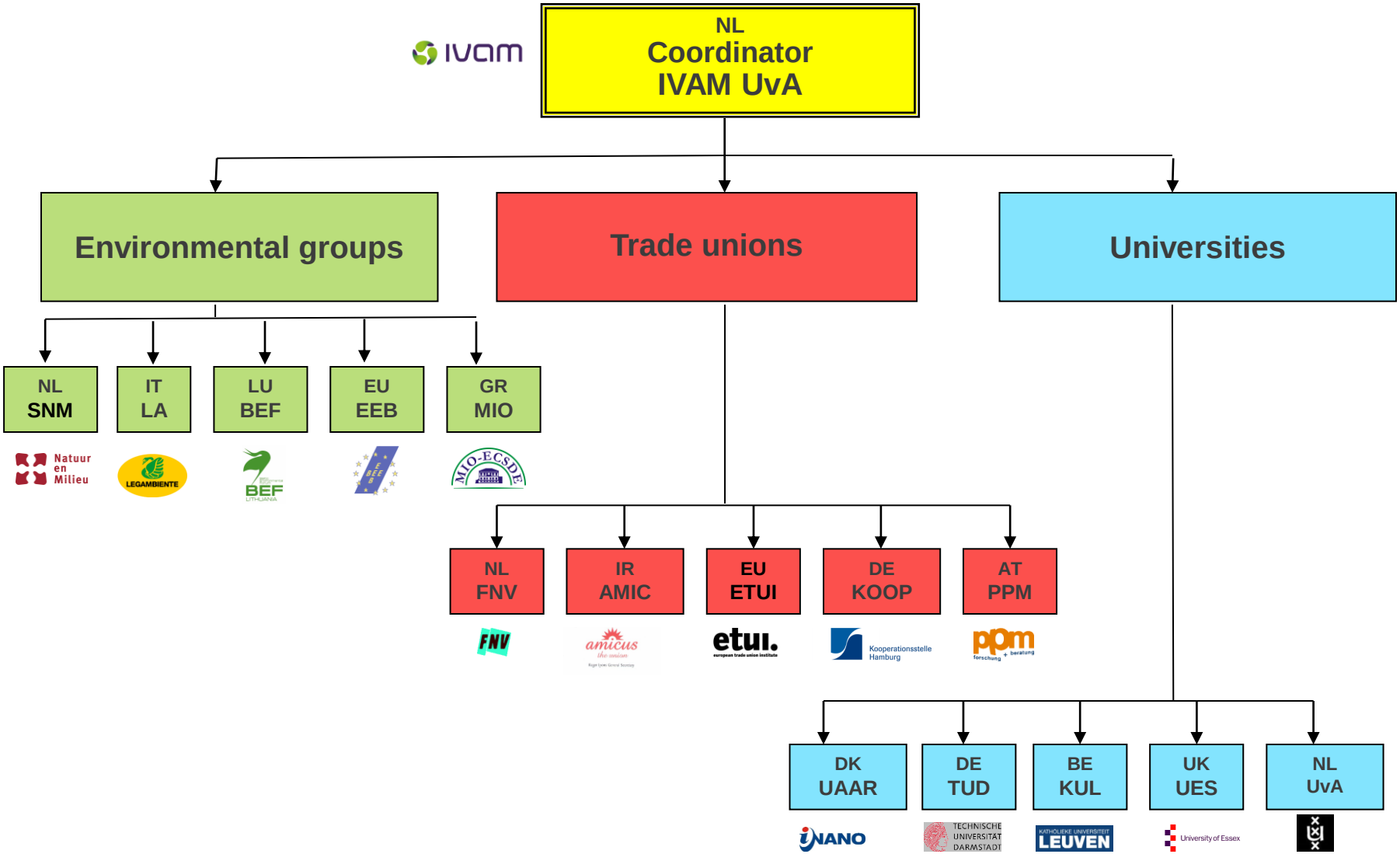
Building the NanoCap team

- ✓ Limited budget (€ 1,3 million)
- ✓ "Reasonable" budgets: 5 x Env NGO's + 5 x TU's + 5 x Univ + 1 x Coordiator
  - ✓ (no further financial possibilities for e.g. consumer organisations)
- ✓ CSOs: broad European representation, incl. 'umbrella' organisations (EEB and ETUI)
- ✓ Universities: representation of most relevant nano-topics

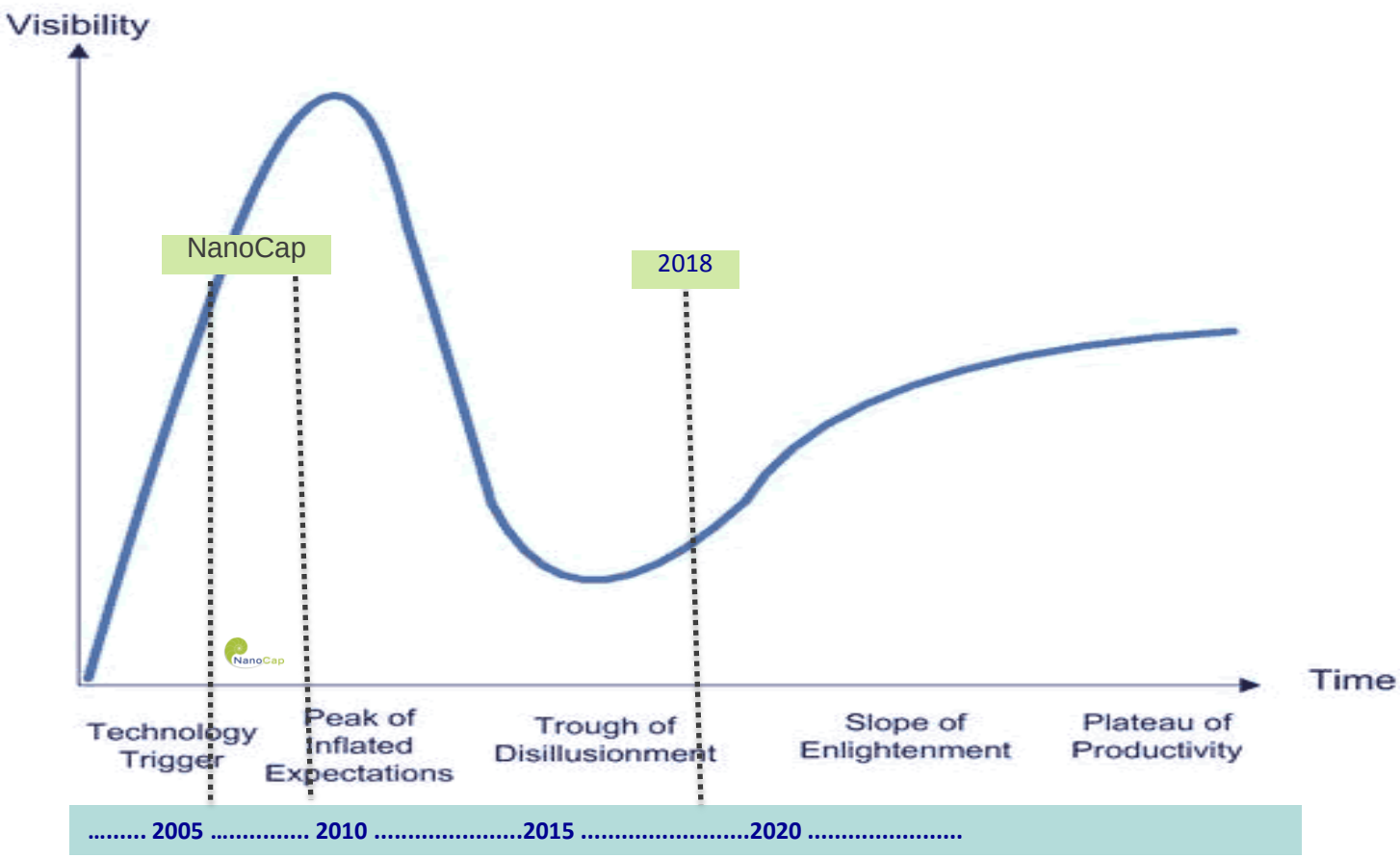
Premises for participation

- ✓ Environmental NGOs
  - *The project should not aim for uniform positions regarding nano governance*
  - *Liberty to disagree with other NanoCap partners' ideas and positionings*
- ✓ Trade Unions
  - *Independent NanoCap team, no commercial interests in nano developments*

NanoCap consortium



Hype Cycle for Nano - Evolutionary Pattern of New Technologies



Capacity building, main activities

✓ *Five working conferences for the NanoCap-team*

- Basics of nanotechnology (**UvA**)
- Technical and physical-chemical nanotechnological issues (**UAAR)**
- Occupational health and safety and environmental issues related to nanoparticles **(UES+KUL)**
- Ethical issues related to nanotechnologies **(TUD)**
- Critical assessment of benefits of nanotechnologies **(IVAM + TUD)**

✓ *Critical discussions within the NanoCap team (e.g. the NanoCapMeter)*

✓ *Workplace visits (BASF, Evonik, Bayer, DSM, Paint industry, Rubber industry)*

Contribution to public nanodialogue

✓ *Discussion with members, authorities, industry and the public*

✓ *Participation in European and (inter)national "nano-debates", and "nano-conferences"*

✓ *Final European NanoCap conference with STOA in the European Parliament*

✓ *Newsletters, policy briefs, NanoVirtualium (MIO), ...*

Positioning of the CSO

✓ *ETUC and EEB resolutions on nanotechnologies and nanomaterials*

Some examples of the The NanoCapMeter (February 2008)

NanoCap

5. EE

NanoCapM

Progress made in achieving your Nano-position

70 %

Relevant issues for the positi

- Nanoparticles in:
  - -Cosmetics
  - -Textiles
  - -Food
- Nanoregulation within REACH
- Codes of Conduct for industries using materials

Missing issues still to be addr

- Codes of conduct
- The reaction of the organic labelig orga Association of UK) for banning manufac products (labeled by them)

Major Identified Barriers

- Scientific information on health effects or environmental ris controversial, no one consolidated scientific opinion

Major Identified Drivers

- Contribution of EEB's Working Group on Nanotechnologie
- Attendance of scientific conferences on nanotechnoogies
- Participation of discussions on nano governance (mostly ir Commission)
- Communication and exchange of positions among NGO cc related issues

NanoCap

9. ETUI

NanoCapM

Progress made in achieving your Nano-position

80 %

Relevant issues for the positi

- COM strategy, Action Plan and Implen nanotechnology
- State of play of the OECD work prgrar
- Development of voluntary initiatives by

Missing issues still to be addi

- Ethical and societal aspects
- Analysis of possible gaps in EU legisla
- Further analysis of possible benefits

Major Identified Barriers

- Complexity of the debate on nanotechnologies
- Lack of expertise among labour organisation

Major Identified Drivers

- Increasing awareness among workers
- Increased collaboration with other stakeholders

NanoCap

12. UAAR

iNANO

NanoCapMeter

Progress made in organizing information supply for NGO's & TU's to formulate their Nano-position statement (%)

75 %

Relevant issues for the position statement

- An understanding of the different aspects of Nanoscience
- Information of potential uses of nanoscience
- Information on how the novel properties of nanotechnology occur
- What gives nanotechnology the potential
- What makes nanotechnology potentially dangerous

Missing issues still to be addressed in NanoCap

- Exposure routes of nanoparticles from nanotechnology
- Toxicology of nanoparticles
- Quantifying nanoparticle release
- Ethical debate around nanotechnology

Major Identified Barriers

- Diversity of nanotechnologies
- Distance between the nanotechnology today and the nanoscience of tomorrow
- Language and terminology
- Background bias of all participants
- Hype around nanoscience

Major Identified Drivers

- Genuine interest of participants
- Nanotechnology is a issue that needs to be addressed now
- Experience from chemical safety
- Perception that there are both potential benefits and potential risks

February 1, 2008

Operationalising the Precautionary Principle

Precautionary Principle in Keywords.....

- Likeliness of adverse effects
- Scientific uncertainty
- Priority for workers safety and environment
- Don't wait for the effect to occur
- Proportionality
- Seriousness of the potential effect
- Agreed level of protection
- Deliberative process

..... and the dilemma of balancing pro's and con's

- Chances/opportunities
- Costs – Claimed Benefits
- Industrial interests
- Desirability product

- Health /Environmental Risks
- Concern level /uncertainties
- Burden of Proof
- Measures / Timing

Focus on safe working with nanomaterials
Precautionary approach for risk management of nanomaterials

➢ Hazard-based approach

Risk = *Hazard* x Exposure

= Potential harmful health-based effects

- **Hazard assessment**: *toxicity of the substances / materials*
- **Health-based OELs**

- ***Known*** **Hazards for many substances can be quantified**

Precaution

➢ Exposure-based risk assessment

Risk = *Concern* x Exposure

= Anticipated *uncertain* risks … worst case

Concern assessment: Size, shape, solubility, biopersistence
- **Nano Reference Values (NRV)**

Concern used for *unknown (assumed) hazards*:
- Nanoparticles *without* established hazard profile, but reasonable grounds to assume adverse effects

NRVs
1. Asbestos-like nanofibres ……0,01 f/cm3
2a. High density granular NP…… 20.000#/cm3
2b. Low density granular NP…….40.000#/cm3
3. Soluble NP…….existing OEL

The Ethics Portfolio for Nanotechnologies - NanoCap

ETHICS PORTFOLIO

Contents and structure
This is the first instalment of a loose-leaf dictionary. It presents separate articles that vary in length but are rather short. Each article has the same structure: Title and key word, introduction and main text, references.

The articles are independent of each other and do not require any special order – but they include cross-references and links. The collection will be online by July 1, 2009. It can be accessed through the NanoCap website or directly at www.nanoOffice.eu

The portfolio is a work in progress. It is open for suggestions, proposed corrections or additions, and submissions of new entries.

There are 4 different types of sheets

- basic ethical concepts *(that play an important role in different fields of applications, e.g. privacy)*
- concepts as tools *(important for understanding nanotechnology as a societal phenomenon, e.g. green nanotechnology)*
- case studies *(like "Magic Nano", the bathroom cleansing product, or water)*
- regulatory issues *(political issues and questions of governance, e.g. codes of conduct)*

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TECHNISCHE UNIVERSITÄT DARMSTADT

TUD, Stefan Gammel et al. 2009

Basic Ethical Concepts

- Future and Present
- Speculative Ethics
- Justice
- Justice & Nano
- Ethics and Morality
- Nano-Ethics
- Privacy
- Values

Concepts as tools

- Green Nanotechnology
- Incredible Tininess
- The programme of Nano
- NanoMachinery

Case Studies

- Green Nano in the US
- Water
- Magic Nano
- Nano Race

Regulatory Issues

- Code of Conduct
- Observatory
- 'Soft' Regulation

Trade unions resolutions on nanomaterials (2008 and 2010)

European Trade Union Confederation (ETUC)
Confédération européenne des syndicats (CES)

ETUC RESOLUTION ON NANOTECHNOLOGIES AND NANOMATERIALS

Resolution adopted by the ETUC Executive Committee in their meeting held in Brussels on 24-25 June 2008

ETUC RESOLUTION ON NANOTECHNOLOGIES AND NANOMATERIALS June 2008

- Apply the precautionary principle
- 15% budget for risk research
- Life cycle approach for release
- "No data no market"
- Use different metrics for Reach registration
- Assure funds for civic participation in debate

for nanotechnologies in the United States and Europe alike has risen steadily year on year. The European Union, for example, has decided to put 3.5 billion euros into nanotechnology research between 2007 and 2013 on top of private sector investment and national research budgets. The most frequently cited estimate is that the world market in nanotechnologies will amount to 1 000 billion dollars by 2015[2].

In terms of employment, it is claimed that nanotechnology development is likely to require an additional two to ten million workers across the world by 2014. Many of these jobs are likely to be created in Europe,

[1] Usually somewhere between 1 nm and 100 nm. A nanometer (nm) is equal to one billionth of a metre.
[2] The economic development of nanotechnology, European Commission, 2006 http://cordis.europa.eu/nanotechnology

ETUC resolution adopted by the Ecexutive Committee on 25 June 08 1

https://www.etuc.org/documents/etuc-resolution-nanotechnologies-and-nanomaterials#.WoK3n7Zx-L4

European Trade Union Confederation (ETUC)
Confédération européenne des syndicats (CES)

ETUC 2nd resolution on nanotechnologies and nanomaterials

Adopted at the Executive Committee on 1-2 December 2010

ETUC 2nd RESOLUTION ON NANOTECHNOLOGIES AND NANOMATERIALS, December 2010

- Allocate funding for societal and ethical concerns
- Implementation of the precautionary principle
- Applicabilion and revision of existing regulations
- Adapt REACH to 'nanomaterial' = new substance
- Transparancy and traceability
- Register of workers' exposure to nanoparticles

The ETUC stated unequivocally that changes resulting from the introduction of nanotechnologies in the workplace should not create further inequalities between workers. The development of nanotechnologies will depend on the skills of people with different backgrounds who will require an interdisciplinary perspective. It has already been recognised that there is a need to upgrade a range of skills, and that it will also be necessary to create new ones, and to educate and train workers in a wide range of sectors.

The number of products on the market containing nanomaterials has been growing substantially[1] and yet there are no updated figures on the risks to human health and the environment. The ETUC called for transparency and traceability of nano-articles placed on the market, which in effect means that there is a need to know whether nanoparticles are contained in products and materials, and if so, what type.

[1] PEN Inventory (2010) http://www.nanotech

John Monks, General Secretary
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https://www.etuc.org/IMG/pdf/13-GB_final_nanotechnologies_and_nanomaterial.pdf

EEB position paper on nanotechnologies and nanomaterials
Small scale, big promises, divisive messages 2008

EEB position paper on nanotechnologies and nanomaterials

Small scale, big promises, divisive messages

February 2008

Background

Nanotechnologies are a set of technologies applied on the atomic and molecular scale of matter that aim to create materials within that size range. A nanometre (nm) is one billionth, or 10^{-9} of a metre. To put this size into context, a nanometre compared to a metre is the same as a marble to the size of the Earth. Other size examples are a width of an average human hair at 100,000 nanometres, and a strand of DNA at 2.5 nanometres.

Nanotechnologies are part of *convergent new technologies*, which offer synergies between nanotechnology, biotechnology, information technology, and cognitive sciences (such as psychology, neuroscience, biology or computer science). Each of these is currently progressing at a rapid rate, experiencing qualitative advancements, and interacting with more established fields such as mathematics, environmental technologies [1]. Nanotechnology therefore is a catch-phrase for a growing range of activities and uses at the nano-level, although these can be focused more specifically on particles (such as carbon or silver), materials (engineered with nano structures, such as carbon nano tubes that make up carbon nanofibres), and products (from cosmetics to medicines).

From a scientific perspective, nanomaterials cannot be considered as a homogeneous group. Physically and structurally they represent very different substances from each other and from their 'bulk' (or 'normal'-sized) counterparts. Their chemical composition and reactivity are also highly diverse. Therefore when speaking of the potentials, benefits and costs of these technologies, one must have a specific nanomaterial or production technology in mind in a specific application and/or product. Because of this diversity of applications and technologies, this document refers to nanotechnologies or nanomaterials in plural. Similarly, since many materials already exist naturally at the nanoscale, we focus here on *engineered (*also known as *manufactured* or *synthetic*) nanomaterials, that is, materials that are specifically designed and/or produced at the nanoscale.

Research and development, use and marketing of nanomaterials have been accelerating for the last 10 years, with expected growth of the global market in the next decade of at least 100million Euros. Proponents of these technologies claim that they will bring about improvements, providing new products and services, enabling increased and new human personal abilities, and generally reshaping societal relationships through innovation in many different sectors. Possible applications include better targeted medicines, more efficient energy storage and lighting, better insulation materials or enhanced physical characteristics of natural resources. Results include improved medical treatment with reduced side effects of drugs, lower energy use, increased productivity in some industries, and reduced resource consumption. Nanotechnology, therefore, is also being heralded as

1

EEB position paper on nanotechnologies and nanomaterials
February 2008

- Pre-market registration and approval framework
- Public consultation on technological innovation, including nanotechnologies and nanomaterials
- Adequate policy and regulatory framework before further market penetration
- Precautionary Principle as central element
- Prioritise research funding on nanomaterials' effects on nature and humans (80% → 15%)

Some Codes of Conducts NanoCap dealt with

Supporting and critisizing initiatives for the voluntary Codes of Conduct, as ‘soft’ law

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 07/02/2008
C(2008) 424 final

COMMISSION RECOMMENDATION

of 07/02/2008

on a code of conduct for responsible nanosciences and nanotechnologies research

GENERAL PRINCIPLES EC-CoC
for guaranteeing respect by all stakeholders

3.1 Meaning
3.2 Sustainability
3.3 Precaution
3.4 Inclusiveness
3.5 Excellence
3.6 Innovation
3.7 Accountability

EN 1

Respons

The Responsible Nano Code – U

The Working Group of the Responsible Nano Code has final
for Responsible Nanotechnology and a series of *Examples of*
the starting point for a more detailed *Benchmarking Framew*
assess the extent to which organisations involved in the rese
of products using nanotechnologies are operating according
developed over the next 5 months.

The Responsible Nano Code will therefore work in two ways:

1. Organisations will be encouraged to adopt the Seve
Code. They can also refer to the Examples of Good P
how each Principle might be implemented. In additi
designed to assess the extent to which they are achi
continuously improve.
2. A group of organisations (to be determined) involve
possibly thereafter, be benchmarked to assess the
according to this Framework; this may include bo
adopt the Code. The intention is for this benchmar
independent group of stakeholders (to be defined).

The Code and the benchmarking process are intended to stim
and continuously improve all aspects of their involvemen
governance, risk assessment, broader social and ethical issue
of their stakeholders.

Following the agreement of the Seven Principles of the Cod
on May 13th 2008, the Working Group convened a Benc
Crossley of Insight Investment. This will develop the detail
Practice - and develop the Benchmark process.

This Sub Group intends to complete its work by the end of
Code and Benchmarking Framework will be formally launch
will undertake the benchmarking process identified. Organi
Code from now on; we expect that the first Benchmarking pr

See below the Seven Principles of the Responsible Nano Code

For a full explanation of the process through which the Co
document *"Information on the Responsible Nano Code Init*
with the Record of Deliberations for the Working Group me
on the website www.responsiblennanocode.org.

For further information on the Responsible Nano Code, please contact Hilary Sutcliffe at Responsible Futures on 0208 693 0053 or email hilary@responsiblefutures.com

EN

Code of Conduct Nanotechnology

BASF The Chemical Company

Risk Framework

Environmen
Nan

Along with offering opportunities, all new technologies also pose risks and this is true for nanotechnology, too. In order to tap into the opportunities offered by technological progress, we want to use new technologies when manufacturing innovative and market-grade products. Only on the basis of these concrete products can a rational assessment be conducted of the potential risks, compared with the opportunities, these products pose. This means that only the willingness to pursue opportunities and risks on a gradual basis will make innovations based on new technologies possible. As an innovative company, we have within this process a special responsibility towards our employees, customers, suppliers and society but also towards future generations. This code of conduct spells out the principles on which our work is based.

1. We, the employees of BASF, develop and use the potential of nanotechnology in order to manufacture products with enhanced performance or new properties using targeted production and the use of new, nanoscale materials.

- The protection of human life and the environment is a fundamental principle for our company.
- We identify sources of risk for our employees in our laboratories, production plants, packing facilities and storage facilities and eliminate these using the appropriate measures. In the event of any health and environmental hazards arising as a result of our operations, we take immediate action.

DUPONT The miracles of science™

ENVIRONMENTAL DEFENSE finding the ways that work

Building blocks for a precautionary approach

• **Precautionary exposure and emission control** *No data → no exposure* *No data → no emission*
• **Derivation of occupational exposure limits (OELs)** for nanomaterials *provisional Nano Reference Values (NRVs)*
• **Registration** of possibly exposed workers
• **Early warning system** development
• **Traceability** of nanomaterials in products *Compulsory reporting of nanomaterials in products*
• **Transparent communication** about known and unknown risks
• **Pre-market approval of** nanomaterials and applications

The follow-up

Nano-skilled CSOs active as critical 'nano-advocates'

- ✓ **CSOs involvement in nano in REACH**
- ✓ **CSOs involvement in ISO/CEN**
  - Development of standard tests, procedures and technical reports
  - Control Banding
- ✓ **CSOs involvement on governance nano-issues (some examples)**
  - Products (nano in cosmetics, nano in food industry)
  - Nano in Social Dialogues (Construction Industry, Wood and Furniture Industry)
  - Nano and occupational exposure limits (OELs): Nano Reference Values
  - Nano and Traceability
  - Guidances for Safe Working with nanomaterials (EU, WHO, DE, NL)

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