



***nanoSTAIR***

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# ***nanoSTAIR***

**Establishing a process and a platform  
to support standardization for  
nanotechnologies**

## **Overview**

# Outline

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1. Standardization of innovations & the STAIR approach
2. Standardization context related to nanotechnologies
3. Concepts of the nanoSTAIR project

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# **1. Standardization of innovations – STAIR**

# Political perspective

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## European standardization conference

"Innovation and market access through standards"  
(Berlin, 27 March 2007)

Günter Verheugen, Vice-President of the EC



- "We must prepare Europe for the rapid political, economic and cultural challenges that affect and threaten us."
- "I can justifiably claim that, as far as European industry is concerned, European standardization is a trump card in global markets."

# Political perspective

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- At the **World Economic Forum** in Davos 2007 the German Chancellor Angela Merkel emphasized the importance of technical standards
  - Standardization has been recognized by the governments as a tool for promoting innovation
  - Research and innovation are to be more closely interlinked with standardization
- ➡ **Goal:** Creating optimum conditions for future innovations and promoting their marketability.

# Promoting innovation

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- EXPRESS recommendations
  - To increase the cooperation between standardization bodies and for a/consortia (strategic goal 9 recommendation)
  - Implementing an integrated approach on standardization, innovation and research
- STAIR – Promoting Innovation
  - Creation of CEN/CENELEC BT working group on Standardization, Innovation and Research (STAIR)
  - Implementing an integrated approach on standardization, innovation and research
  - Promoting the use of the integrated approach in contacts with all stakeholders at the national level
  - Promoting the use of the integrated approach as an efficient tool for European innovation policy
  - Ensuring a better place for standardization issues in Framework Programmes and in their individual calls

# Benefits of European Standards

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- Standardization is an efficient tool for transposing the results of research to support the Single European Market and to strengthen European competitiveness in a global economy
- It fosters technical progress and innovation
- It helps to disseminate awareness and knowledge
- It helps to share good practices among all stakeholders, including:
  - industry at large & small and medium-size enterprises
  - public authorities and regulators as standards users
  - academia and the research community
  - consumers, etc
- It provides an opportunity for better regulation:
  - 'Self regulation' by the market and best practice benchmark
  - A co-regulation approach in Europe since 1985

# STAIR: a step by step process

Think about the  
'standardization  
potential'  
at every step of  
the proposal  
development





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## **2. Standardization context related to nanotechnologies**

# Standardization needs for NOAA (nano-objects aggregates and agglomerates)

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- CEN, has started standardization work on
  - classification, terminology and nomenclature
  - metrology, measurement and characterization (including procedures for calibration),
  - health, safety and environmental issues,
  - and nanotechnology products and processes.
- EC mandates to CEN & CENELEC:
  - Mandate M/409 for the elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials (report dated May 2008).
  - Mandate M/461 requesting to develop the standardization deliverables listed in Annexes I and II of the mandate, and in particular (2010)

# Standardization needs for NOAA

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- Mandate M/461 identifies four areas for standards development:
  - Methodologies for nanomaterial characterization in the manufactured form and before toxicity and ecotoxicity testing;
  - Sampling and measurement of workplace, consumer and environment exposure
  - Methods to simulate exposures to nanomaterials
  - H, S & E (health, safety and the environment)
- The first three of which are covered in Annex I and the fourth in Annex II of the mandate M/461.

# Standardization needs for NOAA

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- ***Annex II - Health, Safety, and Environment***

## Elaboration of a series of guidances: (examples from the list)

- Guidance on safe handling of manufactured nanoparticles and other nanoscale entities;
- Guidance on a common data-format for an integrated analysis for risk assessment;
- Guidance on integrated testing strategies (ITS) and integrated risk assessment;
- Guidance on detection and identification of nanoparticles and other nanoscale entities;
- Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.
- Guidance on nano-material characterization prior to, or in association with toxicity testing;
- Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities;
- Validated test methods for in vivo toxicology and toxicokinetics of nanoparticles and other nanoscale entities;
- Protocols for in vitro toxicology evaluation of nanoparticles and other nanoscale entities;
- Protocols for evaluating the effects of short and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanoparticles and other nanoscale entities;
- Fast track protocols for predicting the toxicity and ecotoxicity for classification of nanoparticles and other nanoscale entities, particularly for identifying and tracking the most dangerous ones in the framework of the REACH directive;
- Protocols for determining the explosivity and flammability of nano-powders (for transport, handling and storage);
- Protocols for risk assessment of potentially hazardous nanoparticles and other nanoscale entities;
- Protocols for risk management that specifically refers to potential nanotechnology hazards;
- Protocols for whole life cycle assessment of nanoscale materials, devices and products.

# List of TC concerned by the mandate M/461

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- CEN/TC 137 Assessment of workplace exposure to chemical & biological agents
- CEN/TC 138 Non-destructive testing
- CEN/TC 162 Protective clothing including hand and arm protection and lifejackets
- CEN/TC 195 Air filters for general air cleaning
- CEN/TC 230 Water analysis
- CEN/TC 352 Nanotechnologies
  
- ISO/TC 24/SC4 Particle characterization
- ISO/TC 142 Cleaning equipment for air and other gases
- ISO/TC 194 Biological evaluation of medical devices
- ISO/TC 201 Surface chemical analysis
- ISO/TC 202 Microbeam analysis
- ISO/TC 229 Nanotechnologies
  
- IEC/TC113 Nanotechnology standardisation for electrical and electronic products and systems

# Perspectives

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- Still necessary to promote standardization activities in the research community
- Provide support to researchers to orient themselves in the standardization activities
- “Close the gulf” between research and standardization by providing more opportunities for linkage
- In concrete:
  - Implement / Use the STAIR approach
  - Develop a platform to inform, connect and start standardization activities based on research results

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## **3. Concepts of the nanoSTAIR project**

# nanoSTAIR overview

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- Title: ***Establishing a process and a platform to support standardization for nanotechnologies implementing the STAIR approach***
- From Sept. 2012 to March 2014
- *...to build a sustainable process and platform in the field of nanotechnologies to support the transfer of knowledge gained through research to documentary standards in the context of the STAIR approach*



Finnish Institute of  
Occupational Health

EUROPEAN COMMITTEE  
FOR STANDARDIZATION



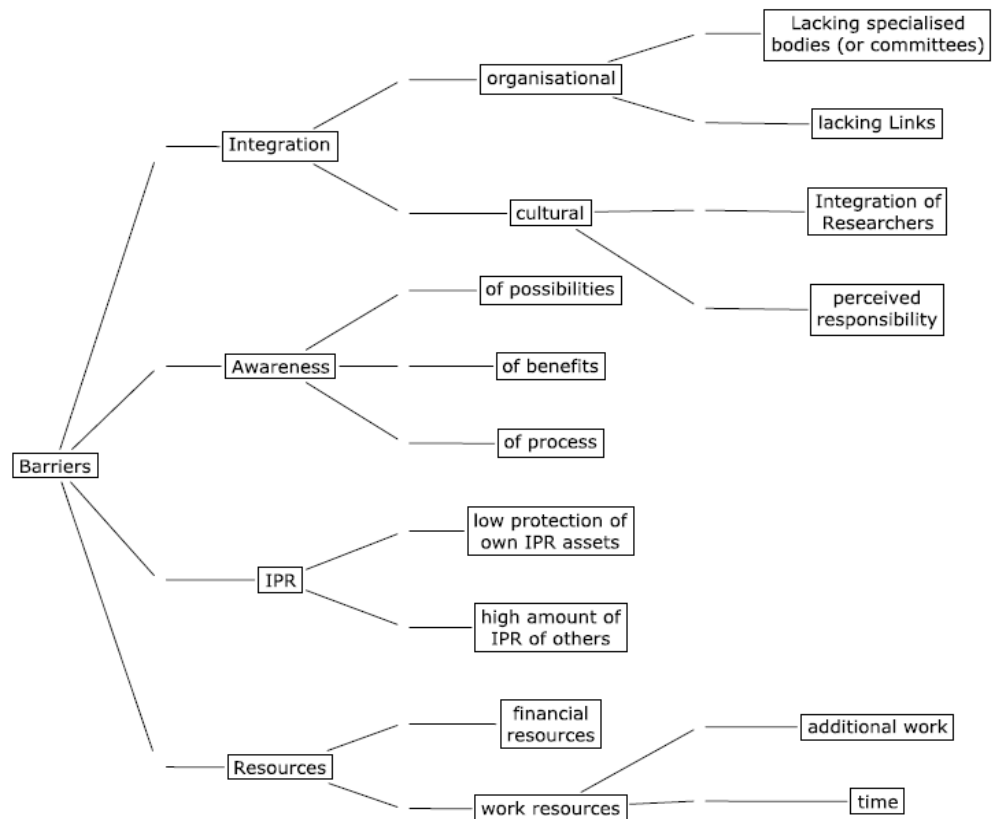


# nanoSTAIR overview

- Scope: All nanotechnologies with opportunities related to “Characterization of and exposure from nanomaterials” and “Health, Safety, and Environment”

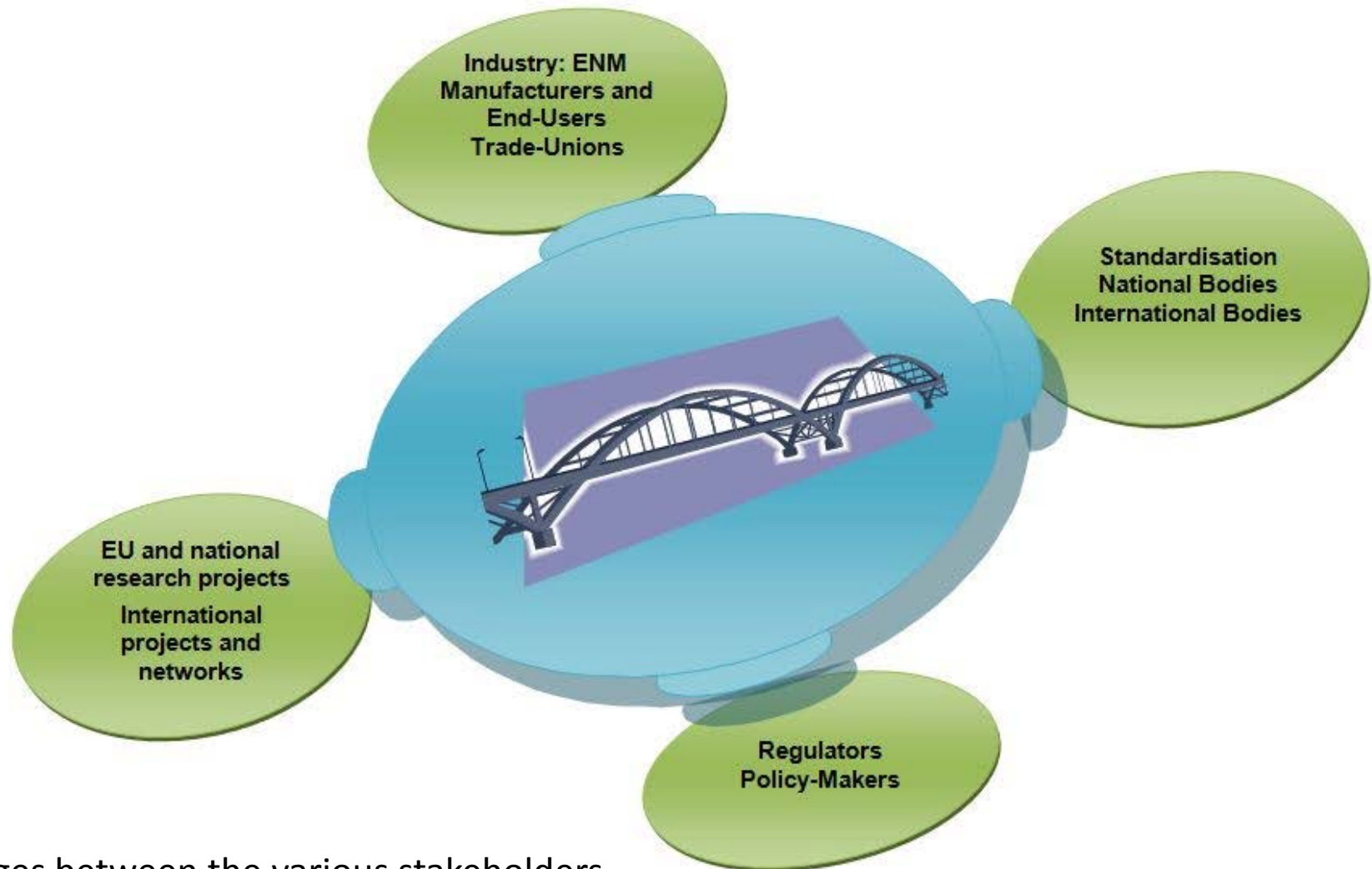
- Barriers addressed

Taxonomy of barriers in the transfer from research to standardization (from INTEREST project D05)



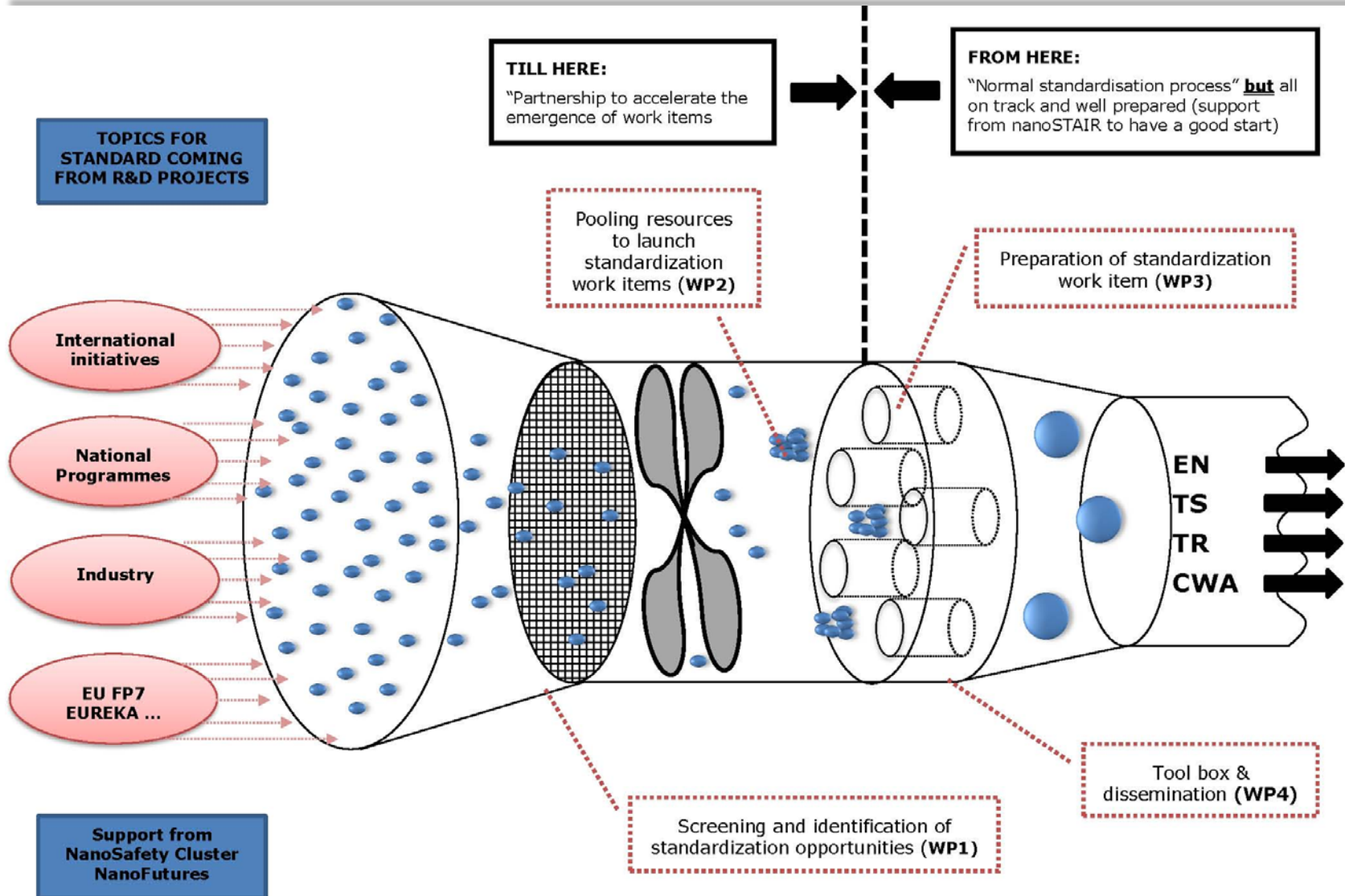
# nanoSTAIR platform

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Bridges between the various stakeholders

# nanoSTAIR turbine



# International Advisory Board

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- Jean-Marc Aublant, CEN TC Chair Person
- Michael Stintz, Member of ISO TC 229 / Chair of the Standardization of NANOofutures
- Georg Reiner, CEN TC 352 Chair of the Strategy Group
- Göran Lindén, CEN TC 137 WG
- Daniel Bernard, ARKEMA
- Hans-Georg Horn, TSI
- Jean-Paul Dufour, CILAS
- Iseult Lynch, Qnano
- Michael Riediker, NanoImpactNet
- Lang Tran, MARINA
- Rudolf Reuther, NANOVALID
- Kirsten Rasmussen, European Commission, Joint Research Center
- Christelle Saout, University of Namur

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# Summary

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- Standardization related to the safety of ENM will support the spreading of good practices and rationalize the communication between the authorities and the industry, and other stakeholders
- The European Standardization Bodies and the European Commission encourage the development of standards linked with research performed at EU level
- In the field of the safety of nanoparticles, the Mandate M461 is an opportunity to coordinate the work
- nanoSTAIR is an vehicle to coordinate the efforts related to standardization linked to projects in the field of nanotechnologies

# Relevant references

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- EXPRESS Report  
[http://ec.europa.eu/enterprise/policies/european-standards/files/express/exp\\_384\\_express\\_report\\_final\\_distrib\\_en.pdf](http://ec.europa.eu/enterprise/policies/european-standards/files/express/exp_384_express_report_final_distrib_en.pdf)
- STAIR Approach  
<http://www.cen.eu/cen/Services/Innovation/STAIR/Pages/default.aspx>
- Mandate M/461  
[ftp://ftp.cenelec.eu/CENELEC/EuropeanMandates/M\\_461.pdf](ftp://ftp.cenelec.eu/CENELEC/EuropeanMandates/M_461.pdf)
- Nanodevice project  
<http://www.nano-device.eu/>
- European Technology Platform on Industrial Safety  
<http://www.industrialsafety-tp.org/>
- NanoFutures  
<http://www.nanofutures.eu/>
- Nanosafetycluster  
<http://www.nanosafetycluster.eu/>
- Commission Nanotechnologies homepage  
<http://cordis.europa.eu/nanotechnology/>  
[http://ec.europa.eu/nanotechnology/index\\_en.html](http://ec.europa.eu/nanotechnology/index_en.html)

# Further information

<http://www.nanostair.eu-vri.eu/>



[nanostair@eu-vri.eu](mailto:nanostair@eu-vri.eu)



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